Air*Life*® nCPAP System

Hardware Service Manual
Driver Model 006900
Firmware Version 2.02

Cardinal Health
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MAINTENANCE & REPAIR

This manual includes procedures used when repairing or replacing parts and components of the Air*Life*® *nCPAP* System Driver, Catalog Number 006900, not covered by warranty and is intended for use by a competent, fully qualified Service Engineer or Technician.

Note:

Always disconnect the machine from facility power, oxygen and medical air before performing any maintenance procedures.

1. PRODUCT DESCRIPTION

The Air*Life*® nCPAP System Driver provides continuous positive airway pressure (CPAP) for use in hospitals to treat spontaneously breathing newborns and infants with Respiratory Distress Syndrome (RDS), or those recovering from RDS under the supervision of qualified personnel (e.g., respiratory therapist or nurse). The driver operates on medical grade air and oxygen. The device has an internal battery and can be used for intra-hospital transport, but is not intended for use in ambulances or aircraft.

The Air*Life*® nCPAP System Driver incorporates an electronic gas blender using solenoid valves and servo-controlled flow to maintain a user-set CPAP pressure and FiO_2. The user interface displays oxygen concentration, CPAP level, flow rate, trending, power, and alarm conditions. The device utilizes both audible and visual indicators for alarm conditions, including text on the LCD display to help the clinician interpret and correct alarm conditions.

The Air*Life*® nCPAP System Driver utilizes a long-life ultrasonic oxygen sensor and automatically performs a two-point oxygen sensor calibration each time the instrument is powered on. The device automatically performs routine Oxygen Sensor Drift Checks/Calibrations during operation at 20 minutes, 40 minutes, and every 12 hours thereafter after power up.

The device requires both medical air and oxygen in order to pass the Power-On Self Test and enter Patient Treatment Mode (the main screen). Due to the nature of the electronic pressure control and gas blending, the device only delivers gas while it is powered on. When turned off, no gas flow exits the Patient Circuit Connection or Oxygen Sensor Bleed Port.

The Air*Life*® nCPAP System Driver is part of a larger system that includes an nCPAP generator, fixation device, and patient interface (prongs and/or masks). This system has been designed and tested with Approved Accessories (see Table of Contents) and will perform optimally when used with accessories provided by Cardinal Health, Inc.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

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2. PRODUCT SPECIFICATIONS

2.1 Modes of Operation

Non-Invasive nasal Continuous Positive Airway Pressure (nCPAP)

2.2 Pneumatic Supply

Required Supply Gases: Clean, dry, medical air and oxygen using standard DISS fittings regulated between 41 – 66 psig (nominal 50 psig). External pressure regulators must be used if source pressures exceed 66 psig.

WARNING

Water, excessive water vapor, or debris in the air or oxygen supply gases may cause the driver to malfunction.

The gas blender and monitoring system are designed for medical grade air and oxygen only. Do not modify the inlets to accommodate other gas sources.

2.3 CPAP Pressure Control / Monitoring

Pressure Control Range: 2 – 10 cm H_2O

Monitor Range: 1 – 11 cm H_2O, accuracy ±1 cm H_2O. Pressure is displayed as <1 or >11 when outside this range.

2.4 Oxygen Control / Monitor

Display Range: 21% – 100% O_2

Alarm Monitoring Range: 17% – 104% O_2

Tolerance ±3% of full scale

Sensor Type: Long Life Ultrasonic

Note:

Driver must be used in combination with external monitoring of patient. Per AARC Clinical Practice Guidelines for the application of CPAP therapy to neonates, monitoring includes periodic blood gas value sampling, continuous noninvasive blood gas values via transcutaneous O_2 and CO_2 monitors, continuous noninvasive SaO_2 values by pulse oximetry, as well as continuous electrocardiogram and respiratory rate measures.

2.5 Flow Monitoring

Range: 0 – 15 lpm, accuracy ±10% of Full Scale

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2.6 Power Supply

Required Power Supply: 15 V DC, 3.3 A, AC adapter (Included, GlobTek, Inc. Model number GTM21097-5015) or an internal 12 V sealed lead/acid battery (included).

The battery has a working time of four (4) hours from a full charge. Battery charging is active when the driver is connected to an AC outlet regardless of whether the driver is turned on or off. The battery requires up to 16 hours of charging to ensure a full charge.

While in operation using battery mode, the battery voltage is monitored and displayed as a percentage of the 4-hour battery life in increments of 25%. Low battery alarms occur at approximately 24 minutes of operation remaining (Medium Priority alarm) and at approximately 12 minutes of operation remaining (High Priority alarm).

CAUTION

The correct AC adapter must be used with the driver. Use of an incorrect AC adapter can damage the internal circuits of the driver.

WARNING

The use of any power cords with the Air*Life*® nCPAP System Driver other than those supplied with the driver may result in increased emissions and/or decreased Immunity of the Air*Life*® nCPAP System Driver.

2.7 Connections for Accessories

Patient Circuit Connection: Standard 15mm Conical/Tapered ID fitting

Proximal Pressure Port: 4.5 mm Luer Compatible ID fitting

2.8 Weight

Approximately 15 pounds

2.9 Dimensions

8-1/2 x 8-1/2 x 6-1/2 inches (excluding gas inlets, patient outlets, and mounting brackets)

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2.10 Pressure Relief

The Driver is equipped with two pressure relief systems. Both systems are self-resetting if the high pressure condition is resolved.

Electronic — An automatic vent valve system preset to vent to ambient air when a High Pressure alarm (patient pressure) occurs.

Mechanical — An internal relief valve is preset to vent if circuit drive pressure exceeds 211 ±11 cm H_2O (3 ± 5% psig).

2.11 Flow Limit

The Driver includes an electronic flow limit to prevent the delivery flow from exceeding 3 lpm over Target Flow, or 15 lpm, whichever is lower. The Target flow may be increased by the operator to compensate for larger leaks. The Driver has a High Priority Low Flow Limit alarm that activates if the measured flow rate is < 3 lpm.

2.12 IEC 60601-1 Classification

Internally Powered Equipment, Type BF, IPX 1. This equipment is rated for continuous operation. This equipment is not suitable for use in the presence of flammable anesthetics.

CAUTION

Although this device meets the requirements of current EMC/RFI legislation, this does not guarantee immunity from all sources of radiated energy. Some mobile telephones and other products containing radio transmitting components may cause a malfunction of the device and should not be used in the vicinity of the device.

2.13 Storage and Operating Conditions

- Safe for storage at -20°C to +60°C
- Relative humidity of 15% to 95% non-condensing
- Atmospheric pressure 0.6 to 1.4 Bar.
- Operating environment temperature is +5°C to +40°C
- Keep dry and do not expose to direct sunlight
- This product meets the EMC requirements of IEC60601-1

WARNING

The patient accessories for use with the Air*Life*® nCPAP Driver are for single patient use only. Disposable accessories include generators, fixation device, prongs, masks, heated wire breathing circuits, and humidification chambers.

DO NOT STERILIZE OR REUSE

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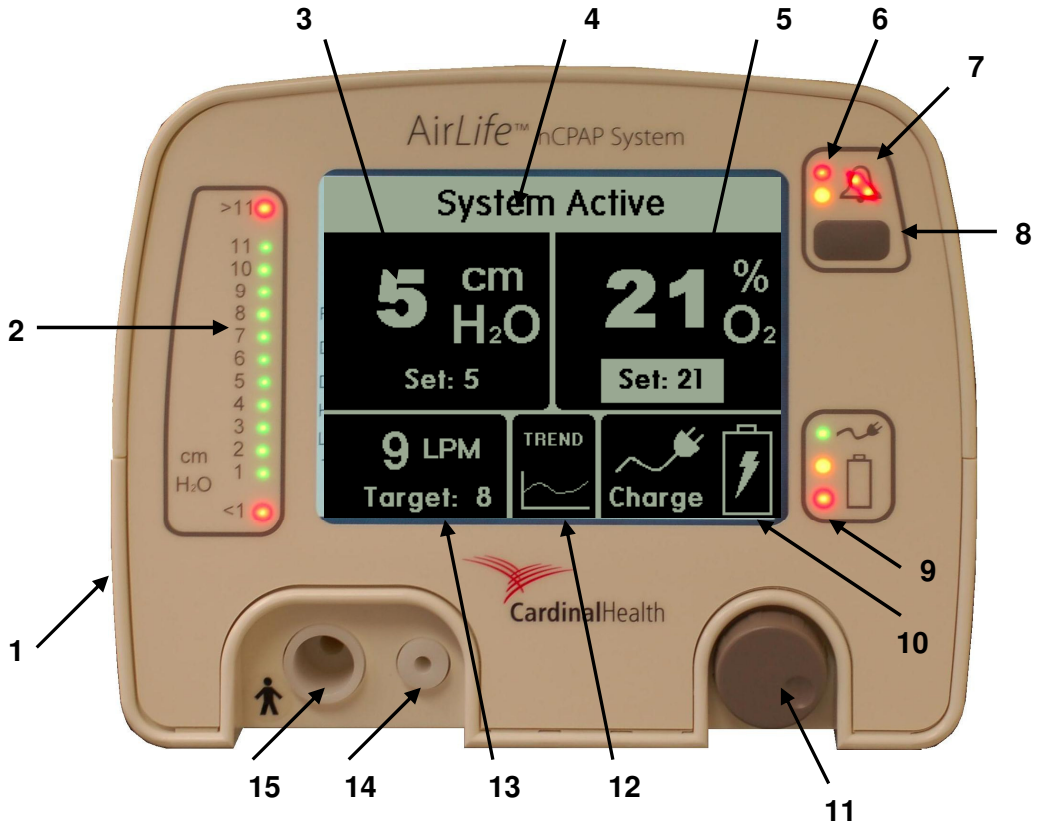
3. DRIVER FEATURE DIAGRAMS

Figure 1: Front Panel Features



Item	Description
1	Protective housing
2	Pressure LED Bar Graph (Indicates instantaneous patient pressure)
3	Pressure Display (Indicates average patient pressure)
4	Message Bar
5	FiO_2 Display
6	Alarm Priority LEDs (Fault LED on top; Warning LED on bottom)
7	Alarm Mute LEDs
8	Alarm Mute/Reset Button (Press & Release for Mute/Reset or to clear a latched alarm; Press & hold for Standby Mode)
9	Power LEDs
10	Power Status
11	Control Knob (Turn to scroll; Push and release to accept)
12	Trend Selection
13	Flow Display
14	Proximal Pressure Port- Standard 4.5mm Luer compatible ID
15	Patient Circuit Connection- Standard 15mm ID, conical

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Figure 2: Rear Panel Features

Item	Description
1	Power Connection
2	Fuse (Fast acting; 3.0 Amp; 250 Volt; size: 5 x 20 mm)
3	Power Switch (Switch does not disconnect driver from main power supply)
4	Medical Oxygen Inlet
5	Medical Air Inlet
6	Serial Number
7	Nationally Recognized Testing Laboratory (NRTL) Classification

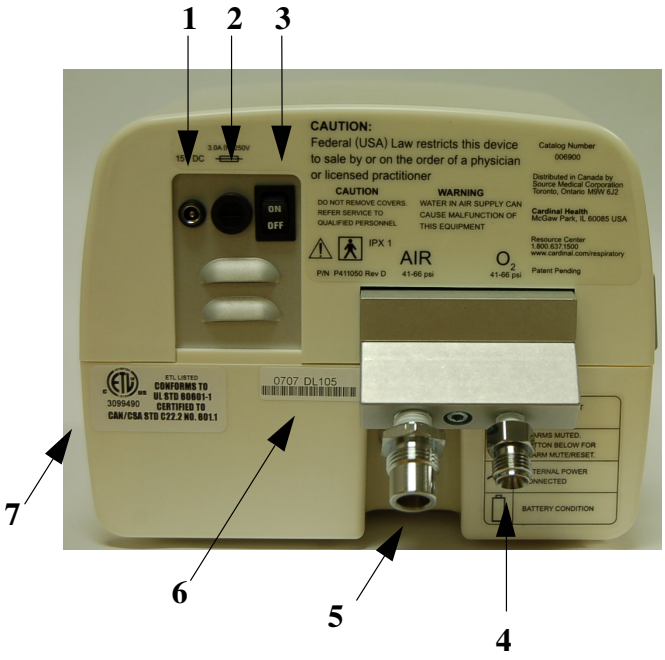
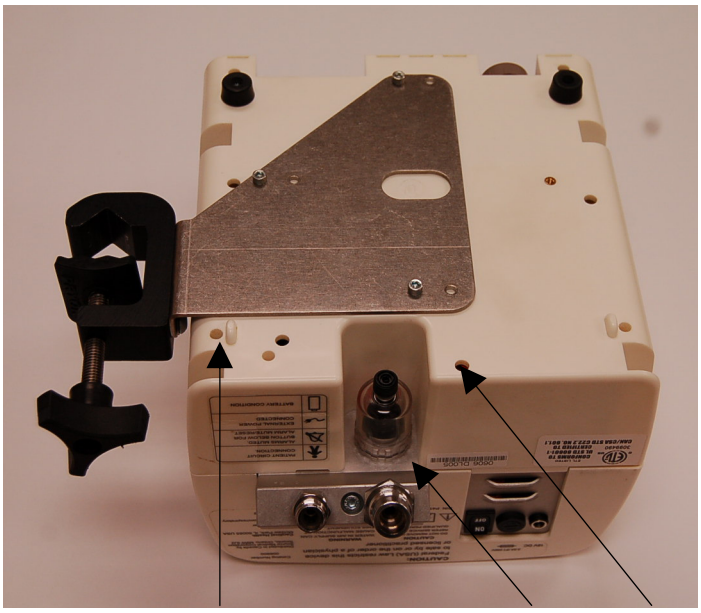


Figure 3: Underside Features

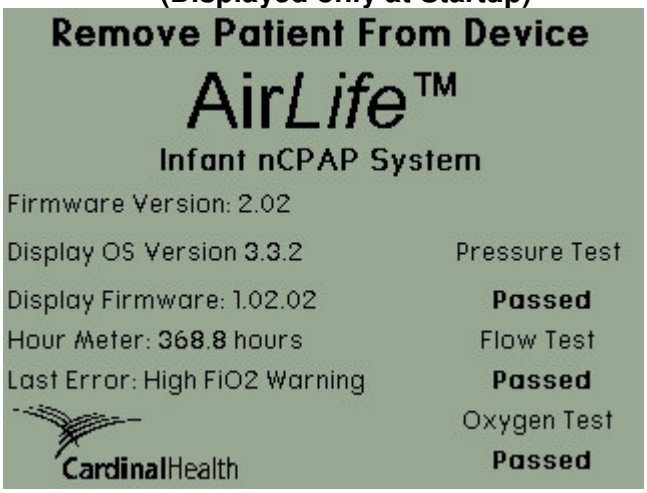
Item	Description
1	Water Trap and Air Filter
2	Oxygen Sensor Bleed Port (do not block)
3	Ventilation / Drainage Holes (do not block)



(6 places)

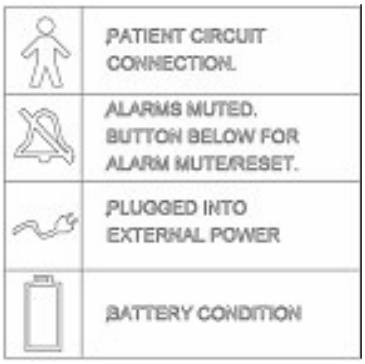
Figure 4: Splash Screen

(Displayed only at Startup)



Example Screen

Figure 5: Icon Legend


PATIENT CIRCUIT CONNECTION.
ALARMS MUTED. BUTTON BELOW FOR ALARM MUTE/RESET.
PLUGGED INTO EXTERNAL POWER
BATTERY CONDITION

4. ALARM SYSTEM

Alarms are delayed for 120 seconds after entering Patient Treatment Mode (the main screen) in order to allow time for patient setup. If the patient setup takes longer than 120 seconds, the alarms can be muted for an additional 120 seconds by pressing the Alarm Mute/Reset button or the system can be placed into Standby Mode.

WARNING

Whenever a patient is attached to respiratory care equipment, constant attendance is required by qualified personnel.
The use of an alarm or monitoring system does not give absolute assurance of warning for every malfunction that may occur in the system.

4.1 Non-Latching and Latching Alarm Signals

If all High Priority alarm conditions return to normal, the audible alarm turns off, the Red Fault LED switches from flashing to steady lit and the Message Bar continues to display the alarm condition(s). Pressing the Alarm Mute/Reset button turns off the Red Fault LED and clears the Message Bar.

If all Medium or Low Priority alarm conditions return to normal, the audible alarm and Yellow Warning LED clear automatically, and the Message Bar no longer displays the alarm condition(s) and returns to display “System Active” to indicate normal operation.

4.2 Alarm Situations

The following describes the alarm situations that may occur during operation:

4.2.1 Supply Gas Pressure Alarm

An audible and visual High Priority Source Pressure alarm will activate if the inlet pressure of one, or both, of the gas sources are outside of the specified gas supply range. The alarm message will indicate the specific gas source that is out of specification. If a single gas source goes out of range during operation, then only the remaining gas source will be available (air or oxygen) and FiO_2 blending will become inoperable. The user will be able to select either ‘Air Only’ or ‘Oxygen Only’ to allow the unit to operate in single-gas source mode and mute the FiO_2 alarms while the problem is corrected. The system will automatically return to normal operation (blending to the original FiO_2 setting) when the problem is corrected and the source pressures are returned to within the specified range. There is a 1-second delay for this alarm.

4.2.2 High Pressure Alarm

An audible and visual High Priority High Pressure alarm has dual limits. The first limit will activate the alarm when the monitored pressure is greater than or equal to 12 cm H_2O for two (2) seconds. The second limit will activate the alarm immediately when the monitored pressure is greater than or equal to 18 cm H_2O. This alarm automatically activates the electronic pressure relief solenoid and closes the patient delivery solenoid, which instantly reduces the pressure in the patient circuit to zero. Approximately every three (3) seconds, the system will reinstate flow. If the alarm condition has cleared, the unit will operate

normally. If the alarm condition still exists, the 'High Pressure' alarm will cycle through the 3-second loop.

4.2.3 Elevated Pressure Alarm

An audible and visual Medium Priority Elevated Pressure alarm is preset for a CPAP pressure that is 2 cm H_2O above the Set CPAP level. There is a 5-second delay for this alarm.

4.2.4 Low Pressure Alarm

An audible and visual Medium Priority Low Pressure alarm is preset for a CPAP pressure that is 2 cm H_2O below the Set CPAP level. There is a 14-second delay for this alarm.

4.2.5 Disconnect Alarm

An audible and visual Medium Priority Disconnect alarm is preset to detect a pressure line or patient interface that has come loose or that is disconnected. The alarm is set to activate when both conditions are met according to the following chart:

Measured Flow (lpm)	Measured CPAP (cm H_2O)
≥ 0	≤ 1
≥ 6	≤ 2
≥ 9	≤ 3
≥ 12	≤ 4
≥ 14	≤ 5

While the alarm is active, the patient flow will remain within ±2 lpm of Target Flow. There is a 5-second delay for this alarm.

For example: if the measured flow rate is ≥ 6 lpm **AND** the CPAP Level is ≤ 2 cm H_2O for a period of five (5) seconds, a Medium Priority alarm will activate.

4.2.6 Leak Alarm

An audible and visual Medium Priority Leak alarm is preset for a flow rate that is 3 lpm above the Target Flow rate or for a flow that is greater than 15 lpm. There is a 5-second delay for this alarm.

4.2.7 Low Flow Alarm

An audible and visual High Priority Low Flow alarm is preset for flow rates at or below 3 lpm. There is a 10-second delay for this alarm.

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4.2.8 Oxygen Concentration Alarms

The oxygen concentration is allowed to operate within a ±3 %O2 range without alarming.

A Medium Priority alarm will activate whenever the product of the variance outside of the FiO2 range and the duration (in seconds) of the variance exceeds 20.

A High Priority alarm will activate whenever the product of the variance outside of the FiO2 range and the duration (in seconds) of the variance exceeds 30.

For example: if the Set %O2 is 30% and the reading is 35% for a period of ten (10) seconds, a Medium Priority alarm will activate. In this case the reading is 2 percentage points outside of the ±3 percentage point range. If the Set %O2 is 30% and the reading is 35% for a period of 15 seconds, a High Priority alarm will activate.

4.2.9 Battery Alarms

An audible and visual Low Battery alarm has dual limits. The first limit will activate the Medium Priority alarm when the battery falls below 10% remaining (approx. 24 minutes of battery power remaining). The second limit will activate the High Priority alarm when the battery falls below 5% remaining (approx. 12 minutes of battery power remaining). There is a 2-second delay for this alarm. An audible and visual Battery Charge Fail alarm will indicate if the battery is not charging properly. The system verifies proper charging at start up and routinely during operation. There is a 5-second delay for this alarm.

4.2.10 Oxygen Calibration Alarm

An audible and visual High Priority Oxygen Calibration alarm will indicate if an error occurs during the Oxygen Sensor calibration. A Warning Screen will appear indicating that an error occurred during the Oxygen Sensor Calibration and informing the user to either remove the patient from the device and cycle power or remove the device from service.

While the alarm is active, the driver provides CPAP and FiO2; however, the FiO2 may not be accurate. The system calibrates the Oxygen Sensor during the Power-On Self Test and routinely during operation. There is no delay for this alarm.

4.2.11 Software Fault

An audible and visual High Priority Software Fault alarm will indicate if a software fault is detected. The system will display a fault code, which should be recorded. If the fault is non-fatal, the alarm can be cleared and the system will return to normal operation. If the fault is fatal, the driver will need to be removed from service as soon as possible. There is no delay for this alarm.

4.2.12 Flow/Pressure Sensor

An audible and visual Sensor Calibration alarm will indicate if either the flow or pressure sensor has failed the calibration during the Power-On Self Test. A Warning Screen will appear indicating which sensor has failed to calibrate and informing the user to remove the device from service.

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5. WARNINGS AND CAUTIONS SUMMARY

The Air*Life*® nCPAP System Driver is intended to be operated only by qualified personnel under the direction of a physician. The operator is responsible for reading and thoroughly understanding the provided product documentation.

Definitions to be considered throughout the document:

Warning: Used when the operator or the patient have the possibility of being injured.

Caution: Used when the driver or accessories used with the driver have the possibility of being damaged.

Note: Used for statements that could allow for more efficient or convenient operation or service of the equipment.

The following are warnings, cautions, and notes that will appear within this document. Please become familiar with their content.

WARNING

Water, excessive water vapor, or debris in the air or oxygen supply gases may cause the driver to malfunction.

The gas blender and monitoring system are designed for medical grade air and oxygen only. Do not modify the inlets to accommodate other gas sources.

WARNING

The driver should only be used after qualified personnel or a technician has authorized it for use.

WARNING

Oxygen vigorously accelerates combustion. To avoid an explosion hazard, do not use any instrument or piece of equipment that may have been exposed to oil or grease contamination.

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WARNING

To avoid the risk of fire or explosion, use this device in well-ventilated areas away from flammable anesthetics.

WARNING

When driver is connected to power source, keep cords clear of walkways to avoid possible cord entanglement and strangulation.

WARNING

The use of any power cords with the Air*Life*® nCPAP System Driver other than those supplied with the driver may result in increased emissions and/or decreased Immunity of the Air*Life*® nCPAP System Driver.

WARNING

The patient accessories for use with the Air*Life*® nCPAP Driver are for single patient use only. Disposable accessories include generators, fixation device, prongs, masks, heated wire breathing circuits, and humidification chambers.

DO NOT STERILIZE OR REUSE

WARNING

Whenever a patient is attached to respiratory care equipment, constant attendance is required by qualified personnel.
The use of an alarm or monitoring system does not give absolute assurance of warning for every malfunction that may occur in the system.

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WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

WARNING

Remove electrical power before servicing the unit. The power switch on this unit does not isolate the driver from the AC Adaptor; disconnect the power supply cable to ensure complete isolation.

Disconnect oxygen and medical air.

Eye protection is required when servicing this machine.

WARNING

There is always a risk when using oxygen that the O2 level in the arterial plasma will reach an unacceptable level. This driver should always be used in conjunction with a pulse oximeter to monitor patient status. Oxygen toxicity can be a concern with this device for the intended population if it is used for more than a few hours. Risks include:

- **Absorption atelectasis (collapse of lung tissue)**
- **Hypercapnia (increased carbon dioxide)**
- **Retrolental hyperplasia (which can cause blindness)**

Also, Chemotherapy patients given bleomycin appear to be extremely sensitive to even relatively low levels of oxygen.

WARNING

Use this product only as directed in the product literature to reduce the possibility of nasal and skin irritation, and necrosis.

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CAUTION

The correct AC adapter must be used with the driver. Use of an incorrect AC adapter can damage the internal circuits of the driver.

CAUTION

Although this device meets the requirements of current EMC/RFI legislation, this does not guarantee immunity from all sources of radiated energy. Some mobile telephones and other products containing radio transmitting components may cause a malfunction of the device and should not be used in the vicinity of the device.

CAUTION

Using the driver without the proper filters can allow dirt or moisture to enter the system. This will damage the electronic blender, leaving the unit non-operational.

CAUTION

Ensure that the driver is unplugged from the AC Adaptor and that the power switch is in the "Off" position before cleaning.

The driver will be damaged if any part of it is immersed in liquid or gas, or steam sterilized.

Important: Do not spray down the unit with water or cleaning solutions.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

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CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

CAUTION

Do not block or occlude flow from exiting the Oxygen Sensor Bleed Port as this may damage the internal oxygen sensor or create internal leaks.

CAUTION

Any liquid introduced into the gas supplies will cause malfunction of this driver and the equipment connected to it.

Note:

Always disconnect the machine from facility power, oxygen and medical air before performing any maintenance procedures.

Note:

To enhance patient safety and comfort, use only with heated humidifiers and heated wire circuits. The recommended setting is 37 ºC, 100% RH.

Note:

To obtain maximum battery life, it is recommended that the driver remain connected to an external power source even when it is not in use.

Note:

The driver must have both gases properly connected and within the specified pressure range in order to pass the initial startup sequence. This will enable the driver to perform a valid calibration and ensure accurate FiO_2 delivery.

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Note:

Class 1 LED product.

Note:

Driver must be used in combination with external monitoring of patient. Per AARC Clinical Practice Guidelines for the application of CPAP therapy to neonates, monitoring includes periodic blood gas value sampling, continuous noninvasive blood gas values via transcutaneous O_2 and CO_2 monitors, continuous noninvasive SaO_2 values by pulse oximetry, as well as continuous electrocardiogram and respiratory rate measures.

Note:

Alarms are delayed for 120 seconds after entering Patient Treatment Mode (the main screen) in order to allow time for patient setup. If the patient setup takes longer than 120 seconds, the alarms can be muted for an additional 120 seconds by pressing the alarm mute/reset button or the system can be placed into Standby Mode.

Note:

Hospital personnel should keep records of Performance Verification Tests and Preventative Maintenance, and identify equipment that is authorized for use.

Note:

In-depth Preventative Maintenance is to be performed by a competent, fully qualified service technician or engineer. Preventative Maintenance must be performed at a minimum frequency per the table below.

Note:

Do not replace the Top Case until the Power-On Self Test is complete and the Patient Treatment Mode Screen (the main screen) appears.

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6. APPROVED ACCESSORIES LIST

Component	Company	Catalog Numbers
Disposable Accessories		
Delivery Circuit	Cardinal Health	RC51-12002
	Viasys	CC8112E
	Hamilton	33078
	Fisher and Paykel	RT132
Generator Set (Nasal Prongs are included with the Generator Set)	Cardinal Health	006905
	Viasys	777085-102, 777213, 773386-102 773387-102 11541, 12204, 773388-101, -103 773389-102, -104
	Hamilton	33201
Nasal Mask	Cardinal Health	006925, 006930, 006935
	Viasys	777086-101, 777086-102, 777086-103, 777086-104
	Hamilton	37700, 37701, 37702
Reusable Accessories		
Heated Humidifier	Fisher and Paykel	MR730, MR850
Driver Stand w/ extension pole & basket	Cardinal Health	006995
Stand Power Strip		006996
Stand Tank Holder		006997

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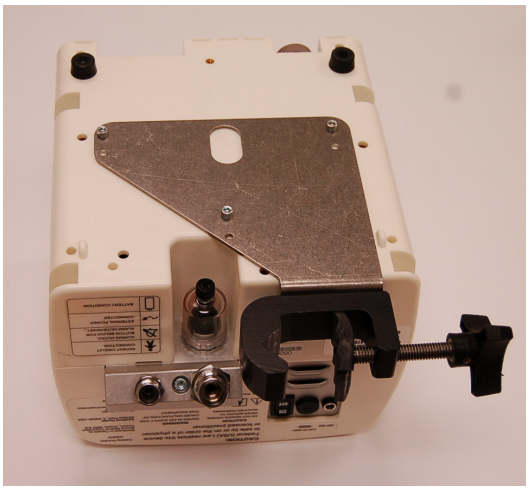
7. DRIVER SET-UP, OPERATION, AND BASIC INSPECTION

7.1 Mounting Bracket and Clamp Assembly

The Mounting Bracket and Clamp Assembly can be installed in two (2) different orientations. Both are depicted below. Removing the Mounting Bracket and Clamp Assembly is not necessary to service the driver.

1. Place nCPAP driver upside down on a clean, dry surface.
2. Use a 9/64" Allen wrench to attach the Mounting Bracket Assembly with the three (3) #8 mounting screws and lock washers included with the driver. Torque the screws to 7 in-lb.



Mounting Bracket and Clamp Assembly, Rear Installation-Standard Orientation

Mounting Bracket and Clamp Assembly, Optional Side Orientation

7.2 Attach Driver to Stand

Securely attach the driver to a stand or other mounting system that includes a heater/humidification system. A Mounting Bracket and Clamp Assembly is included and should be attached to the driver using the supplied hardware. Ensure that the stand is rated to safely handle the weight and dimensions of the driver, as detailed in the "Product Specification" section, or use the recommended stand as listed in the approved accessories list.

The Driver Attached to a Stand

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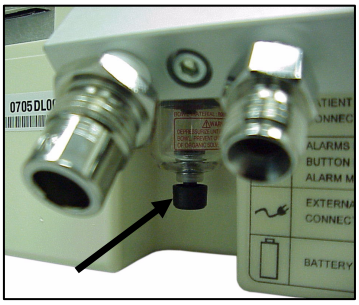
7.3 Inspect Air Filter

Visually inspect the inlet air filter and water trap, located on the back of the driver. If the filter is dirty or wet, it must be cleaned or replaced. A tool is included with the driver to assist in removing the water trap.



Air Filter and Water Trap

7.4 Connect Hoses & Power

1. Connect medical air and oxygen hoses to the back of the driver. Each port is clearly marked. Connect the hoses to their respective high-pressure sources regulated between 41 – 66 psig (nominal 50 psig).
2. Plug the AC Adaptor into the power connector on the back of the driver and a properly grounded AC outlet.
3. Power on unit and verify that all of the LEDs illuminate.
4. Once the driver enters Patient Treatment Mode (the main screen), verify that the following default values are indicated on the main screen:
   - ❑ CPAP Set: 5 cmH_2O
   - ❑ FiO2 Set: 21% O2
   - ❑ Flow Rate Target: 8 lpm
   - ❑ Battery charging (lightning bolt in battery icon)

Power Connector

Note:

Alarms are delayed for 120 seconds after entering Patient Treatment Mode (the main screen) in order to allow time for patient setup. If the patient setup takes longer than 120 seconds, the alarms can be muted for an additional 120 seconds by pressing the alarm mute/reset button or the system can be placed into Standby Mode.

5. Unplug the AC Adaptor, verify a single audible alarm burst sounds and the LCD Display indicates the driver is operating on battery power. Reconnect the AC Adaptor.

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

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7.5 Interaction with Display Settings

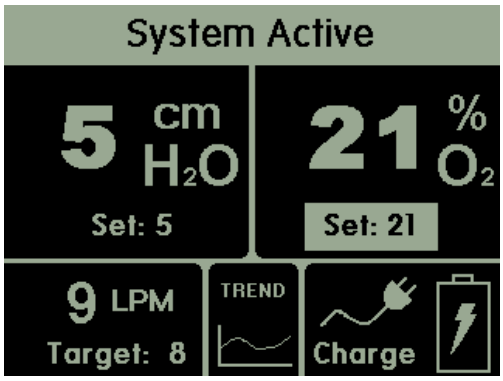
Operating the Control Knob

Control of the various AirLife® nCPAP Driver features is accomplished through the use of the Interface Control Knob.

7.5.1 Control Knob Operation

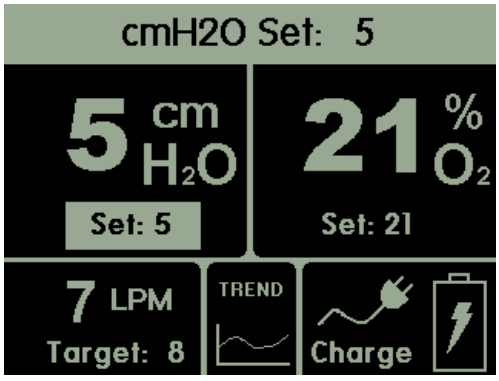
Follow these steps to adjust the $\%O_2$, CPAP, or Flow Target values.

1. Rotate the Control Knob to move the highlight cursor to the different sections of the screen. The default location for the highlight cursor is the Set $\%O_2$.



Main Display Screen

2. Select the parameter by pressing the Control Knob when the section you wish to change is highlighted.
3. A prompt will appear in the Message Bar at the top of the display showing the current settings for that feature. Rotate the Control Knob clockwise to increase the value, counter-clockwise to decrease the value.



Parameter Change Screen

4. When the desired value is displayed in the Message Bar, press and release the Control Knob to activate the new set value. Confirm that the desired setting is displayed as the "Set" value on the main screen. **If the Control Knob is not pressed and released to accept a new value the change will automatically be canceled after ten (10) seconds of inactivity, and the previous setting will remain unchanged.**

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5. The flow rate displayed on the LCD screen indicates the flow rate exiting the Patient Circuit Connection. The "Target" flow is pre-set based on the CPAP setting. The flow is automatically adjusted to maintain the CPAP setting and it may normally vary from the Target flow.
6. The driver will automatically increase flow up to 3 lpm above the Target flow to compensate for normal leaks (i.e. leaks around prongs, masks, or through the patient's mouth).
   - ❑ If a large leak exists at the patient, that cannot be corrected by adjusting the patient interfaces, then the Target flow may be set higher (up to 13 lpm) to provide more flow to compensate for leaks. If the leak is resolved, the driver will automatically reduce the flow to maintain the set CPAP level.
   - ❑ The flow rate should not be less than 3 lpm. A "Low Flow" alarm will activate if the measured flow rate is less than 3 lpm and would indicate a possible occlusion of the expiratory limb or a defective circuit / generator. If this alarm occurs, check for pinched or kinked tubing, or replace the circuit and / or generator.

7.5.2 Standby Mode

Standby Mode allows the operator to mute the alarms for up to 20 minutes while at the bedside attending to the patient. Select this mode by pressing and holding the Alarm Mute/Reset button until there is a single audible burst (approximately 3 seconds). The operator can exit the mode by pressing the Alarm Mute/Reset button or the system will automatically exit the mode and resume normal operation after 20 minutes. While in Standby Mode the system will operate normally with all audible alarms muted, with the exception of High Pressure and Low Flow. To indicate that the system is in Standby Mode, the Message Bar will display "Standby Mode" and the Alarm Mute LEDs will flash. There will also be a single audible burst every two (2) minutes while in Standby Mode. The driver will exit Standby Mode automatically if a High Pressure or Low Flow alarm occurs.

7.5.3 Air or Oxygen Only Mode

While switching Air and Oxygen supply hoses from one source to another (e.g. switching from tanks to wall sources), only change one source at a time. This will help prevent interruptions in fresh gas flow to the patient. The Air*Life*® nCPAP System Driver may be used with a single gas source if one gas source goes outside of the specified pressure range (e.g. running out of gas) during normal operation. During such an event, the driver will alarm and display the source fault in the Message Bar. In the absence of one gas source, the patient can only receive air (FiO_2 ~ 21%) or Oxygen (FiO_2 = 100%). If the fault cannot be corrected immediately, then the user may select "Air Only" or "Oxygen Only" operation in order to mute the alarm while the faulty gas source is corrected. When the faulty source pressure is corrected, the system will automatically return to normal operation (alarms will be delayed for 20 seconds) and blend gases to the previously set FiO_2 value.

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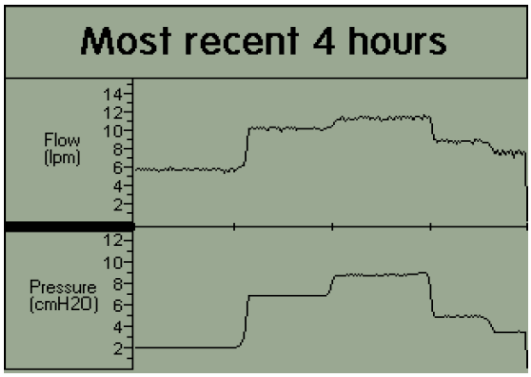
7.5.4 Trending

The Air*Life*® nCPAP System Driver has a Trend Screen. This screen will display data for the previous 4, 8, 12, or 24 hours. Traces are displayed simultaneously on the screen. The Trending Screen will allow the operator to know if there have been any fluctuations in the displayed parameters. Information stored for the previous patient is automatically removed when the unit is powered up. To access the Trend Screen:

1. Rotate the Control Knob until the 'Trend' feature is highlighted.
2. Press and release the knob to activate the Trend Screen.
3. Rotate the knob to select the desired Trending time: 4, 8, 12, or 24 hours. Displayed data are not actively updating.
4. Press and release the knob to return to the main display. The system will also exit the Trend Screen if an alarm condition occurs or after 120 seconds of inactivity.

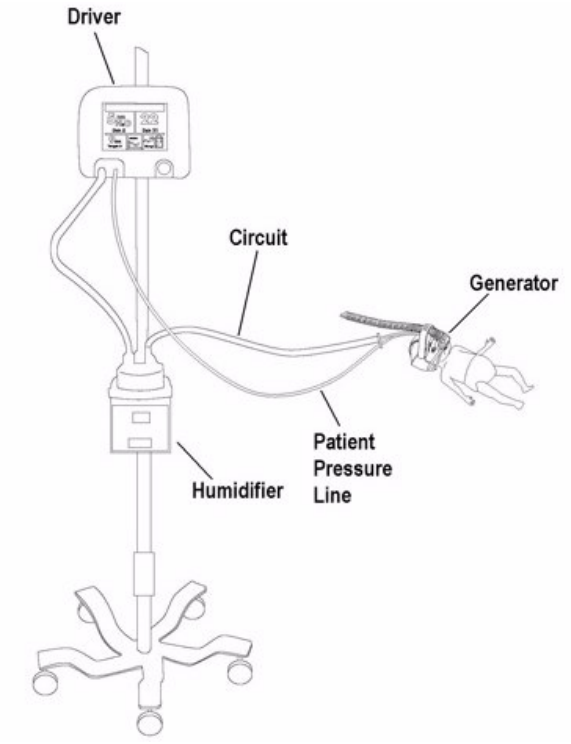


Trending Display on Trend Screen

7.5.5 System Operation

Follow manufacturer's recommended instructions when setting up a patient with the fixation device, generator and patient interface. After the patient has been properly set-up, set the prescribed values for the CPAP level and FiO_2. Connect the pressure line and the drive line of the circuit to the driver.

If an alarm occurs during operation, it should be addressed immediately to ensure that the patient is receiving the proper therapy. Details about the alarms generated by the driver are listed in sections 4 and 15.



Typical Driver Setup

8. ROUTINE CLEANING & SET-UP

Routine cleaning and set-up should be performed before initial use and between patient uses. If the driver fails routine set-up it must be removed from service for a complete service or calibration inspection.

Note:

Hospital personnel should keep records of Performance Verification Tests and Preventative Maintenance, and identify equipment that is authorized for use.

WARNING

The driver should only be used after qualified personnel or a technician has authorized it for use.

8.1 Battery

The battery included in the driver requires no routine maintenance. The driver should remain connected to the AC Adaptor whenever possible to ensure a full charge in case patient transport is necessary and to achieve the expected, useful battery life of two (2) years. The battery must be replaced at least every 2 years.

CAUTION

The correct AC Adapter must be used with the driver. Use of an incorrect AC Adapter can damage the internal circuits of the driver.

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8.2 Unit Inspection and Cleaning

1. Visually inspect the inlet air filter and filter bowl. If the filter is dirty or wet, it must be replaced. A tool is included in the accessories box to assist in the removal of the filter bowl.

CAUTION

Using the driver without the proper filters can allow dirt or moisture to enter the system. This will damage the electronic blender, leaving the unit non-operational.

2. Clean external surfaces with a mild soap or disinfectant. DO NOT USE ABRASIVE CLEANERS.

CAUTION

Ensure that the driver is unplugged from the AC Adaptor and that the power switch is in the "Off" position before cleaning.

The driver will be damaged if any part of it is immersed in liquid or gas, or steam sterilized.

Important: Do not spray down the unit with water or cleaning solutions.

3. Connect medical air and oxygen hoses to the back of the driver. Then connect the hoses to their respective high-pressure sources regulated between 41 – 66 psig (nominal 50 psig). Plug the AC Adaptor into the back of the driver and an AC outlet.
4. Connect a patient circuit, generator, and medium prongs to the driver. Occlude the prongs to prevent disconnect alarms.
5. Turn driver on.
6. Observe that all of the LEDs illuminate when the unit is powered up and running the Power-On Self Test (~45 seconds).
7. Once the driver has entered Patient Treatment Mode (the main screen), verify that the following default values are on the main screen:
   - ❑ CPAP Set: 5 cmH_2O
   - ❑ FiO_2 Set: 21% O_2
   - ❑ Flow Rate Target: 8 lpm
   - ❑ Battery charging (lightning bolt in battery icon)
8. Unplug the AC Adaptor, verify that a single audible alarm burst sounds and the LCD Display indicates the driver is operating on battery power. Indication on the LCD Display includes the Green Power LED ceasing to illuminate, the Plug Icon disappearing and bars appearing in the Battery Icon to indicate the level of available battery life.

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9. Set the $\%O_2$ to 35%, the CPAP Level to 5 cm H_2O (default), and occlude the nasal prongs.
10. Allow approximately twenty (20) seconds for the valves to adjust and verify that the CPAP reading is at 5 ± 1 cm H_2O and that the displayed oxygen concentration is 35 ±3 percentage points.
11. **'Disconnect' alarm test**
    - ❑ Remove the occlusion of the prongs.
    - ❑ Ensure that a 'Disconnect' or 'Low Pressure' alarm activates within 15 seconds.
    - ❑ If a 'Disconnect' alarm is active, verify that the flow settles to within ± 2 lpm of Target Flow.
    - ❑ If a 'Low Pressure' Alarm is active, verify that the flow does not exceed 3 lpm over Target Flow.
    - ❑ Occlude the prongs and verify that the CPAP level returns to 5 ± 1 cm H_2O and the FiO_2 returns to 35± 3% within 20 seconds.

8.3 Disposal

Patient accessories, including the generator, fixation device, prongs, masks, breathing circuit, and humidification chamber, should be disposed of by incineration in order to reduce the risk of contamination.

WARNING

The patient accessories for use with the Air*Life*® nCPAP Driver are for single patient use only. Disposable accessories include generators, fixation device, prongs, masks, heated wire breathing circuits, and humidification chambers.

DO NOT STERILIZE OR REUSE

The battery and LCD display must be disposed of according to local regulations.

9. DRIVER MAINTENANCE SCHEDULE

Note: In-depth Preventative Maintenance is to be performed by a competent, fully qualified service technician or engineer. Preventative Maintenance must be performed at a minimum frequency per the table below using only approved spare parts.

Required Inspection and Replacement Schedules				
Component	**Inspection Schedule**	**Replacement Schedule**		
		Frequency		**Section**
Air filter media (external)	Visual bowl inspection at each start-up	12 months		11.2
Air and O2 Inlet Screens	No routine inspection	12 months		11.3
Power Cord/ AC Adaptor	Visual inspection prior to each start-up; Electrical inspection annually	60 months		n/a
Oxygen Sensor Filters (Internal)	No routine inspection	12 months		12.2
Battery Assembly	Check annually per section 14	24 months		12.4
Manifold Assembly	Check bleed flow annually per section 14	60 months		12.5
Divider/Oxygen Sensor Assembly	Check FiO_2 Accuracy annually per section 14	60 months		12.6
System	Perform Comprehensive Performance Test annually or after any service or repair	n/a		n/a

WARNING

Oxygen vigorously accelerates combustion. To avoid an explosion hazard, do not use any instrument or piece of equipment that may have been exposed to oil or grease contamination.

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10. RECOMMENDED TOOLS AND TORQUE SPECIFICATIONS

The following seven tools should be on hand when repairing the unit:

- 5/32” Allen wrench
- 5/64” Allen wrench
- 9/64” Allen wrench
- 7/16” open end wrench or nut driver
- T-10 Torx Driver
- Air Filter Bowl Removal Tool Assembly (P411197, supplied by Cardinal Health)
- Torque Wrench

The following is a list of the torque specifications to be followed when repairing the unit:

- 5 in-lbs
  - Outlet Fitting Assembly Screw
  - Oxygen Bleed Fitting
  - Top Case Mounting Screws
- 7 in-lbs
  - Manifold Assembly Mounting Screws
- 12 in-lbs
  - Control Knob / Selector Switch
- 15 – 20 in-lbs
  - Inlet Block Screw

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11. PREVENTIVE MAINTENANCE– EXTERNALLY ACCESSIBLE

WARNING

Remove electrical power before servicing the unit. The power switch on this unit does not isolate the driver from the AC Adaptor; disconnect the power supply cable to ensure complete isolation.

Disconnect oxygen and medical air.

Eye protection is required when servicing this machine.

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

WARNING

To avoid the risk of fire or explosion, use this device in well-ventilated areas away from flammable anesthetics.

WARNING

When driver is connected to power source, keep cords clear of walkways to avoid possible cord entanglement and strangulation.

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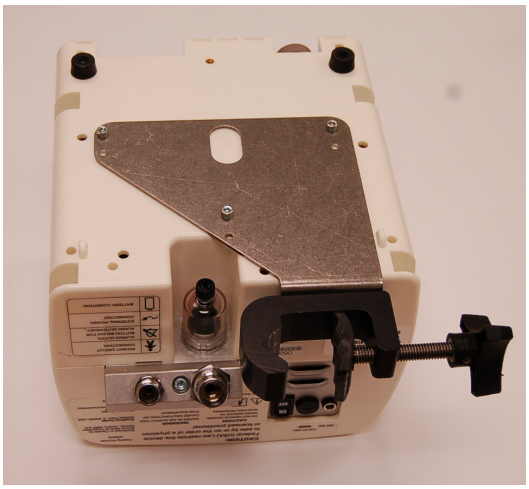
11.1 Mounting Bracket and Clamp Assembly

The Mounting Bracket and Clamp Assembly can be installed in two (2) different orientations. Both are depicted below. Removing the Mounting Bracket and Clamp Assembly is not necessary to service the driver - instructions are included here only if you wish to change the orientation.

1. Place nCPAP driver upside down on a clean, dry surface.
2. Use a 9/64" Allen wrench to remove the (3) #8 mounting screws and lock washers.
3. Reorient the bracket to one of the two positions shown below and reattach using the (3) #8 mounting screws and lock washers.
4. Inspect the rubber feet. Replace worn feet if necessary.



Mounting Bracket and Clamp Assembly, Rear Installation-Standard Orientation

Mounting Bracket and Clamp Assembly, Optional Side Orientation

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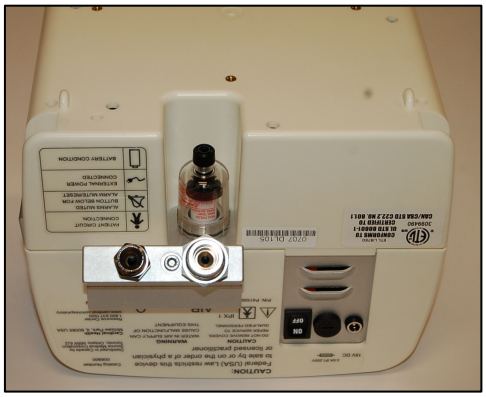
11.2 Air Filtration Maintenance

This air filter bowl and element should be visually inspected at every set-up and replaced per the maintenance schedule or if water or contaminant is detected. This standard 5 micron element (P/N P411182) filters out particulate matter that may be present in the air lines to protect the electronic sensors and proportional valves inside the driver.

1. Visually inspect the inlet air filter and filter bowl. If the filter is dirty or wet, it must be replaced. A white Delrin tool with an Allen wrench has been supplied to assist in the filter bowl removal process (part number P411197).
2. Insert the pronged end of the Filter Bowl Removal Tool onto the filter bowl and gently turn the tool counterclockwise, using the Allen wrench as a handle, until the filter bowl loosens from the housing.
3. Gently unscrew and remove the filter bowl.
4. Using your fingers, gently unscrew the filter retaining nut, and remove and discard the old filter.
5. Place the new filter onto the shaft, and install the filter-retaining nut finger tight.
6. Place the bowl over the filter, and using the Filter Bowl Removal Tool, tighten the bowl onto the housing.



Visually inspect air filter and filter bowl.

Use Delrin tool to remove filter bowl.

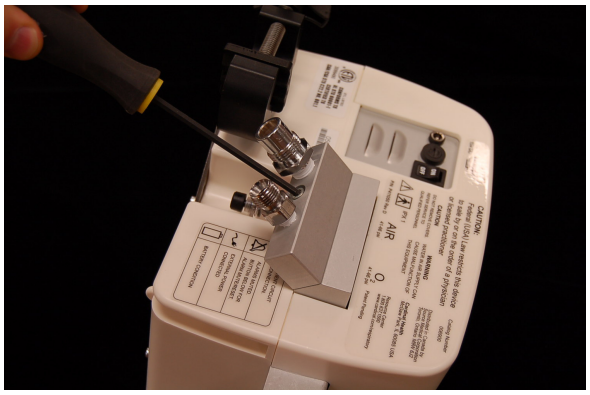
Unscrew and remove old filter.

Place new filter on shaft.

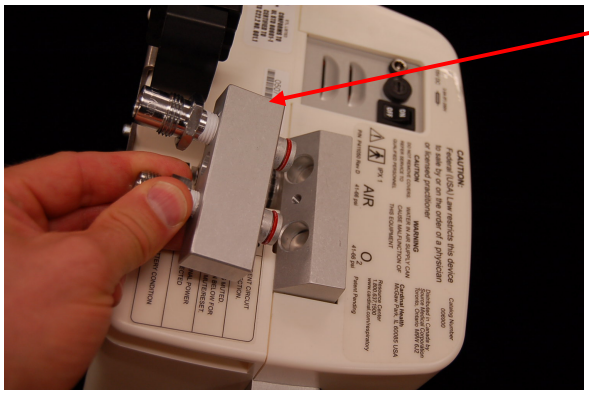
11.3 Air and Oxygen Inlet Screen Replacement

These filter screens (P/N P410895) should be replaced per the maintenance schedule or if the driver exhibits low air and/or oxygen source pressures (indicating the possibility of a clogged inlet screen). These 15-micron stainless steel screens filter out particulate matter that may be present in the air and/or oxygen lines to protect the electronic sensors and proportional valves inside the driver.

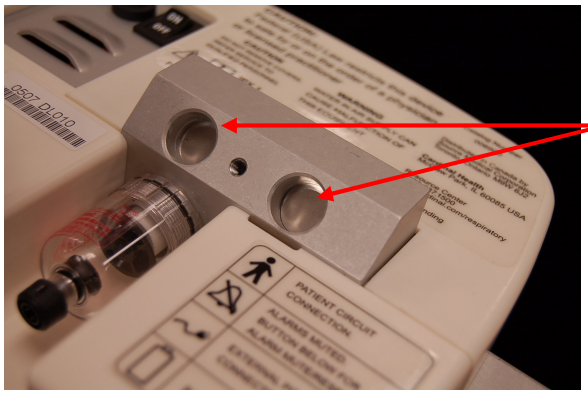
1. Remove the single #10 Allen-head screw, located between the air and oxygen fittings.



2. Slide the Inlet Block out of the manifold, and locate the screen in each manifold port.



3. Replace screens and reassemble the Inlet Block. Be careful not to pinch or damage the o-rings during reassembly – the Inlet Block should slide in easily.
4. Secure the Inlet Block with the #10 Allen-head screw; tighten to a torque of 15 – 20 in-lbs.
5. Inspect the two screens that were removed from the driver. If the screens show obvious amounts of debris or discoloration, then consider investigating the cleanliness of the medical grade gases and increasing the frequency of screen replacements.



11.4 Oxygen Bleed Flow Measurement

The nCPAP driver utilizes a side-sampling of the blended gases to monitor the FiO_2. This flow is referred to as Oxygen Bleed Flow and is channeled and vented outside of the driver via the Oxygen Sensor Bleed Port in the Bottom Case. The Oxygen Bleed Flow must be within specification to maintain the stated FiO_2 accuracy so it must be inspected routinely and after any service or repair. Never occlude the Oxygen Sensor Bleed Port as this may damage the internal oxygen sensor or cause internal leaks.

1. Connect air and O_2 supply gases between 41 – 66 psig, preferably at a nominal pressure of 50 ± 1 psig.
2. Connect a circuit and CPAP generator to the Patient Circuit Connection and Proximal Pressure Port.
3. Power up the driver and allow the unit to perform the Power-On Self Test (this takes ~ 45 seconds).
4. Confirm that the driver passes the Power-On Self Test by ensuring that the driver enters Patient Treatment Mode (the main screen) and that "System Active" appears in the Message Bar.
5. Measure the Oxygen Bleed Flow exiting the Oxygen Sensor Bleed Port, located on the underside left-rear of the driver (refer to Figure 3 in section 3).

CAUTION

Do not block or occlude flow from exiting the Oxygen Sensor Bleed Port as this may damage the internal oxygen sensor or create internal leaks.

6. Normal Oxygen Bleed Flow specifications for inlet pressures at 50 ± 1 psig are 0.9 to 3.0 lpm.
7. To allow for normal variations in inlet source pressure of 41 – 66 psig (and potentially, the unavailability of a breathing circuit and generator), the acceptable Oxygen Bleed Flow specification is 0.7 – 3.0 lpm.
8. If the Oxygen Bleed Flow falls outside of the stated specification, check the plumbing inside the driver for loose connections and/or kinks in the tubing.
9. If the Oxygen Bleed Flow is within the stated specification, then the driver may be released for normal use.
10. If the Oxygen Bleed Flow is not within the stated specification and cannot be corrected, then the driver must be taken out of service and repaired (refer to section 15, Troubleshooting).

11.5 Fuse Replacement

There is one (1) Fast Acting 3.0 Amp 250 V fuse on the rear of the unit. Replace the fuse if blown.

Replace the fuse with a Fast Acting 3.0A 250V fuse.

12. PREVENTIVE MAINTENANCE– INTERNALLY ACCESSIBLE

WARNING

Remove electrical power before servicing the unit. The power switch on this unit does not isolate the driver from the AC Adaptor; disconnect the power supply cable to ensure complete isolation.

Disconnect oxygen and medical air.

Eye protection is required when servicing this machine.

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

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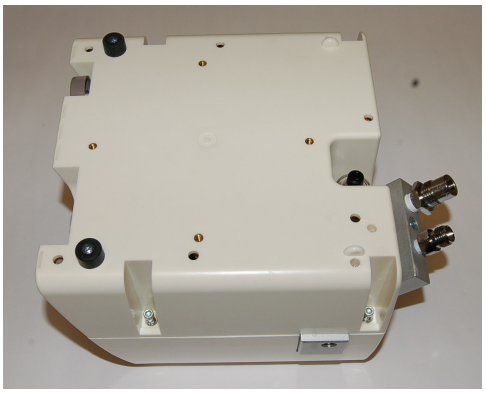
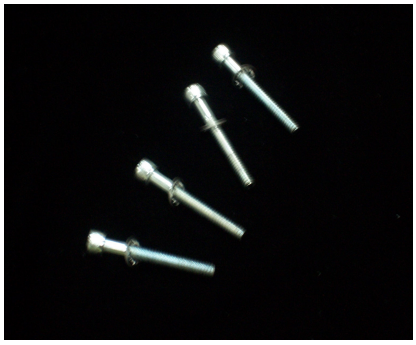
These procedures should be followed in sequence to provide easiest disassembly when access to driver interior is desired.

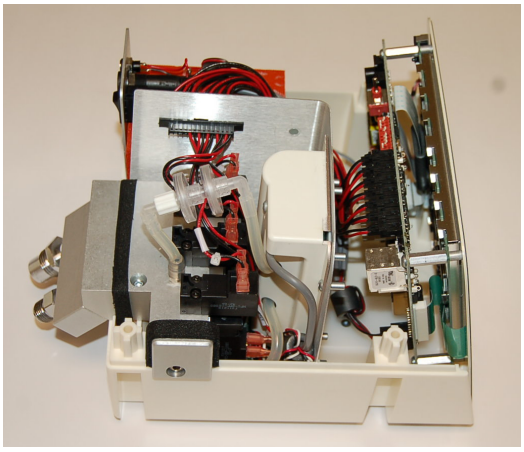
12.1 Remove the Top Case from the Bottom Case

1. Turn the unit upside down on a clean, dry, level surface.
2. Use a 9/64" Allen wrench to loosen and remove the four (4) #8 screws that secure the Top Case to the Bottom Case.
3. Turn the unit right side up and gently pry the Top Case from the Bottom Case. (The Top Case may be difficult to remove due to foam insulation. Be very careful.)





Use a 9/64" Allen wrench to remove the socket-head screws.

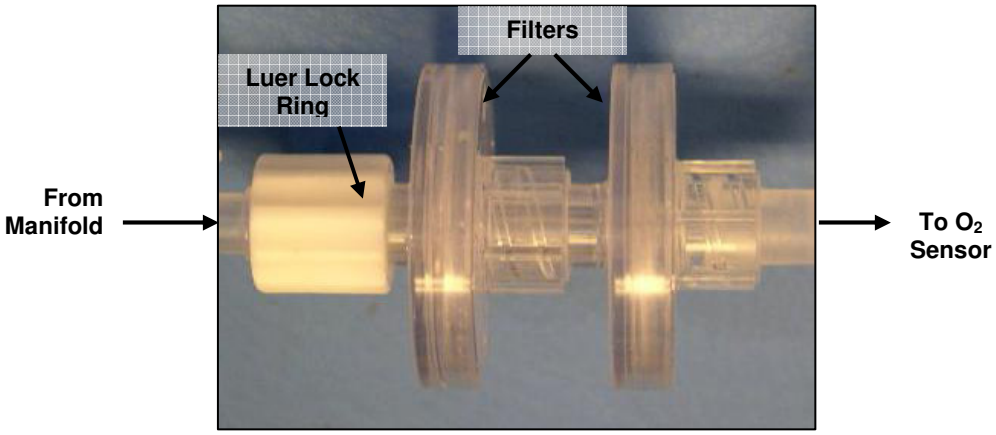


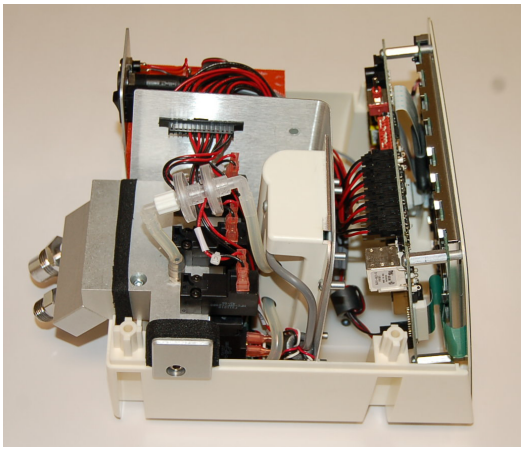
nCPAP driver with Top Case removed.

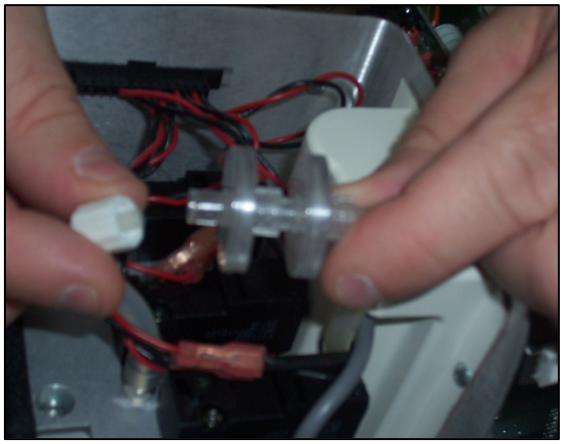
12.2 Replace the Oxygen Sensor Filters

The nCPAP driver has two (2) filters (two required) that provide filtration and signal conditioning for the ultrasonic Oxygen Sensor. They are necessary for stable operation of the Oxygen Sensor and FiO_2 control system. Replace these filters according to the maintenance schedule.

1. Use your fingers to unscrew the white luer lock ring from the Oxygen Sensor Filters.
2. Unscrew the Oxygen Sensor Filters from the Oxygen Sensor Elbow.
3. Lock two (2) new Oxygen Sensor Filters together by twisting the mating ends together about 1/2 turn until snug.
4. Attach the Oxygen Sensor Filters to the Oxygen Sensor Elbow by twisting the filters 1/2 turn until snug.
5. Screw the white Luer lock ring to the conjoined Oxygen Sensor Filters
6. Ensure all joints have remained tight.







When replacing the Oxygen Sensor Filters, ensure that the components are secured finger tight.

12.3 Remove the Front Panel Assembly

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

1. Gently pull the Front Panel Assembly forward so you have room to work.
2. Avoid touching the LCD Backlight Power Supply. If the driver is not powered down and disconnected from the AC Adaptor, the LCD Backlight Power Supply may still be energized.
3. Disconnect the Valve Drive Cable from the Bulkhead to Valves Cable.
4. Disconnect the Power Cable Assembly from J19 on the Main Board (PCA-01).
5. Disconnect the Main to Bulkhead Cable from the Main Board (PCA-01).
6. Disconnect the Control Knob/Selector Switch from J11 on the Main Board (PCA-01).

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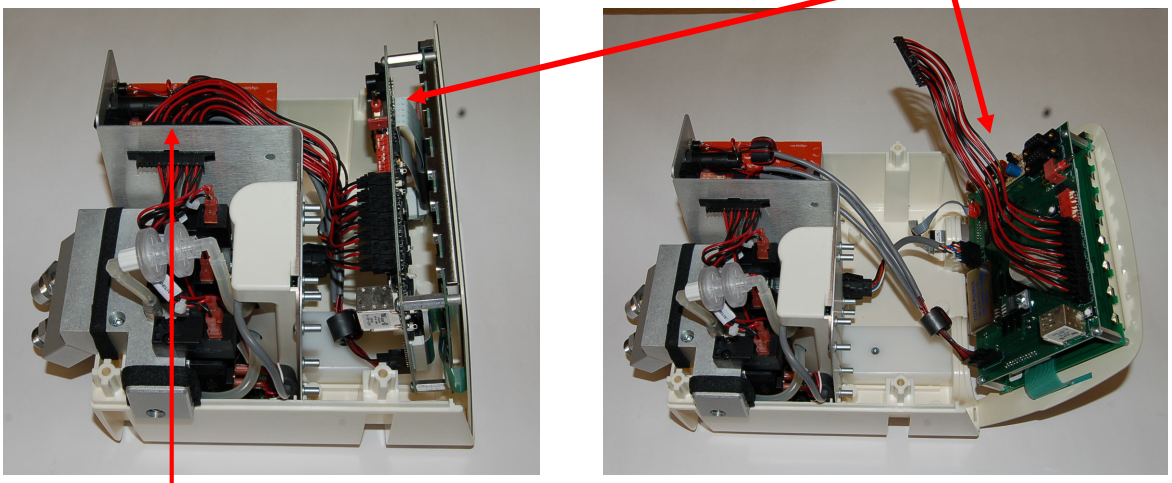
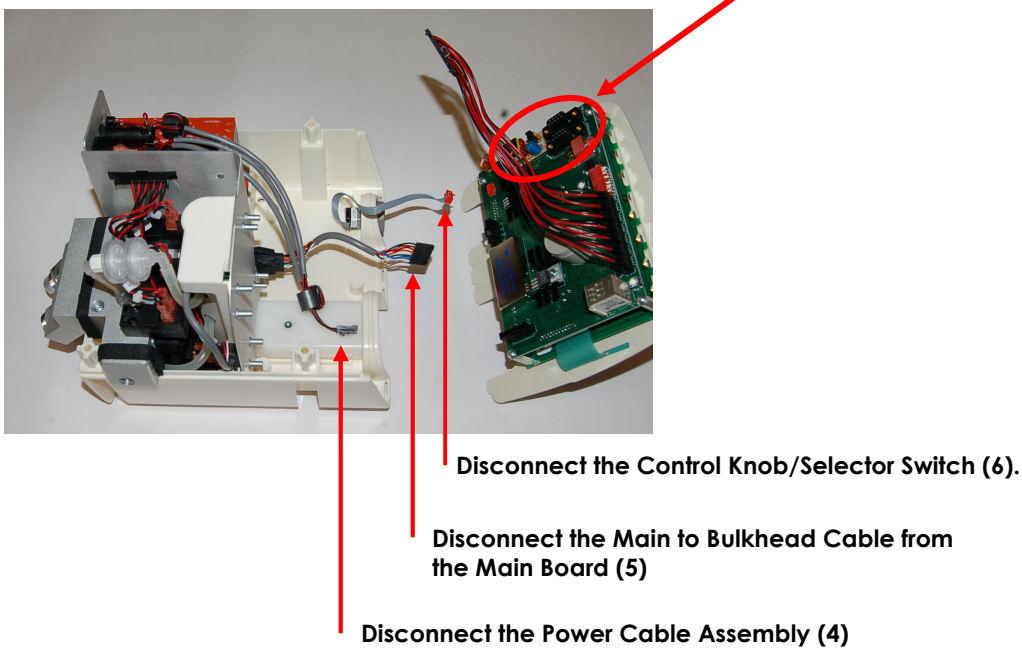
7. Gently lift the Front Panel Assembly from the Bottom Case.




LCD Backlight
Power Supply
Disconnect the Control Knob/Selector Switch (6).
Disconnect the Main to Bulkhead Cable from
the Main Board (5)
Disconnect the Power Cable Assembly (4)

12.4 Removing the Battery Assembly

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

In order to remove the Battery Assembly, the Power Cable Assembly must first be removed.

1. The Power Cable Assembly is mounted at the rear of the Bottom Case, behind the Battery Assembly. It is held in place by friction from the foam pads on the Battery Assembly.
2. Disconnect negative terminal of Power Cable Assembly from Battery Assembly.
3. Gently pull the Power Inlet Panel from behind the Battery Assembly.
4. Disconnect positive terminal of Power Cable Assembly from Battery Assembly.
5. Disconnect Valve Drive Cable by squeezing the Bulkhead Connector's tabs and gently pushing it through the slot in the Divider/Oxygen Sensor Assembly.
6. Gently lift the Battery Assembly from its mount.

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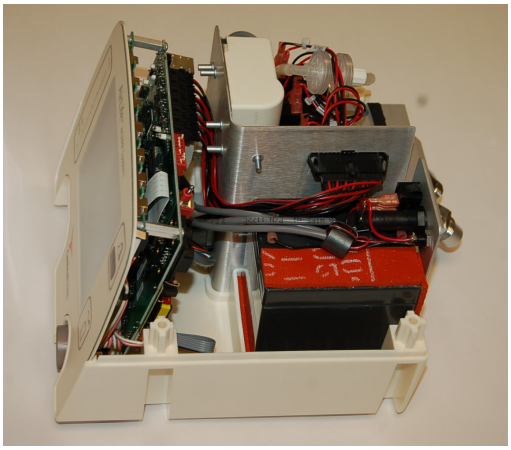
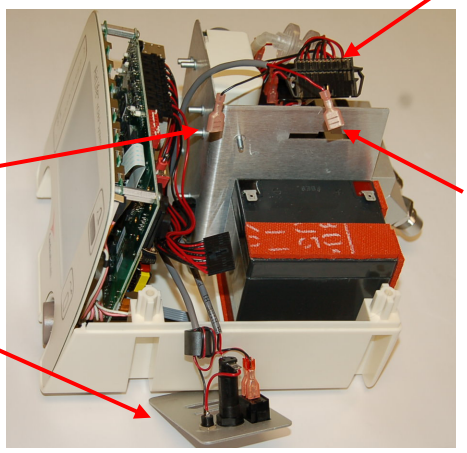
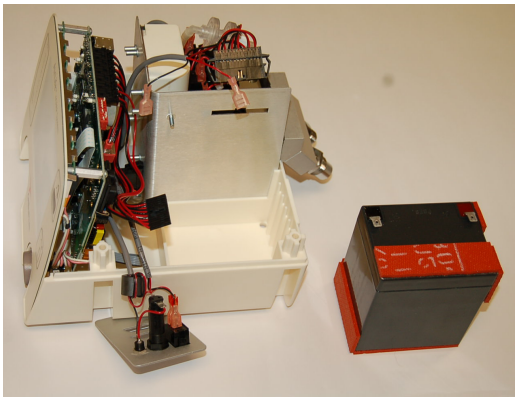
7. Reverse procedure to install replacement battery.
8. ***Always dispose of the battery according to local regulations.***




Push Bulkhead Connector through Divider (5)
Disconnect negative terminal (2)
Disconnect positive terminal (4)
Remove Power Inlet Panel (3)



12.5 Remove the Manifold Assembly

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

1. Disconnect the Valve Drive Cable from the Bulkhead to Valves Cable.
2. Pinch and gently push the connector on the Bulkhead to Valves Cable through the slot in the Divider/Oxygen Sensor Assembly.
3. Disconnect the white luer lock ring from the Oxygen Sensor Filters.
4. Use a 9/64” Allen wrench to remove the two (2) socket-head screws that secure the Manifold Assembly to the Bottom Case.
5. Carefully disconnect the locking tab of wire CN15 from CN21 on the Inlet Pressure Board (PCA-03).
6. Carefully disconnect the locking tab of wire CN16 from CN22 on the Inlet Pressure Board (PCA-03).
7. Disconnect the silicone tubing from the barbed fitting on the underside of the Manifold Assembly.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

8. Gently lift the Manifold Assembly from the Bottom Case.

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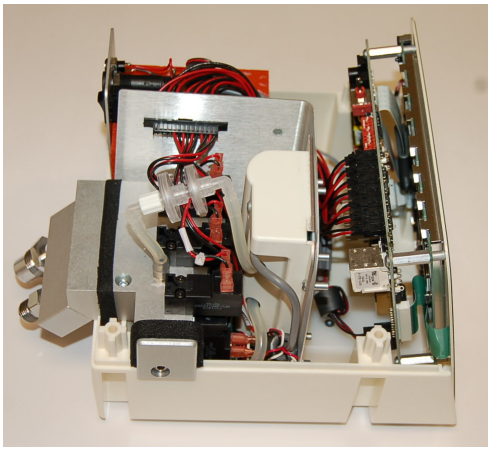
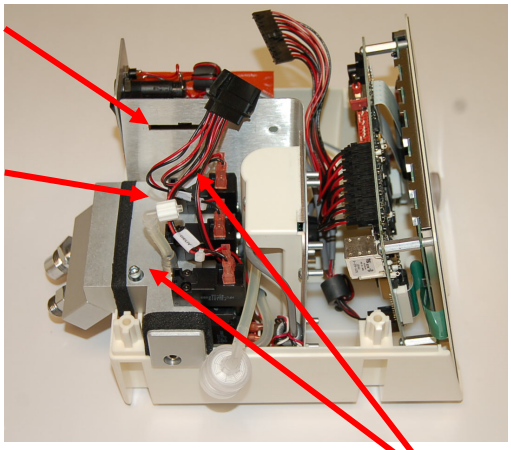
9. Reverse procedure order to install replacement Manifold Assembly (refer to section 13.6).

10. Torque the two mounting screws to 7 in-lbs.

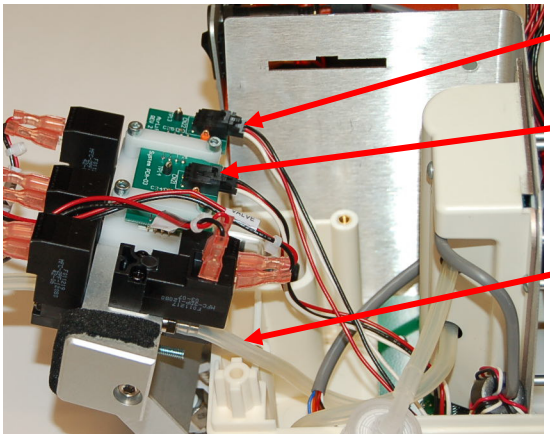


Pinch & push connector through Divider (1)(2)

Disconnect luer lock (3)



Remove 2 mount screws (4)



Disconnect wire from CN22, (6)

Disconnect wire from CN21, (5)

Disconnect silicone tubing (7)

12.6 Remove the Divider/Oxygen Sensor Assembly

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

1. Disconnect the Valve Drive Cable from the Bulkhead to Valves Cable.
2. Pinch and gently push the connector on the Bulkhead to Valves Cable through the slot in the Divider/Oxygen Sensor Assembly.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

3. Tilt the Front Panel Assembly forward to gain access to the Divider/Oxygen Sensor Assembly.
4. Avoid touching the LCD Backlight Power Supply. If the driver is not powered down and disconnected from the AC Adaptor, the LCD Backlight Power Supply may still be energized.
5. Disconnect Main to Bulkhead Cable from Remote Board Bulkhead Cable connector.
6. Pinch and gently push the connector on the Remote Board Bulkhead Cable through the slot in the Divider/Oxygen Sensor Assembly.
7. Disconnect the white luer lock ring from the Oxygen Sensor Filters.
8. Use a 9/64” Allen wrench to remove the two (2) socket-head screws that secure the Manifold Assembly to the Bottom Case. Tilt Manifold Assembly to access the Remote Sensor Board (PCA-02).

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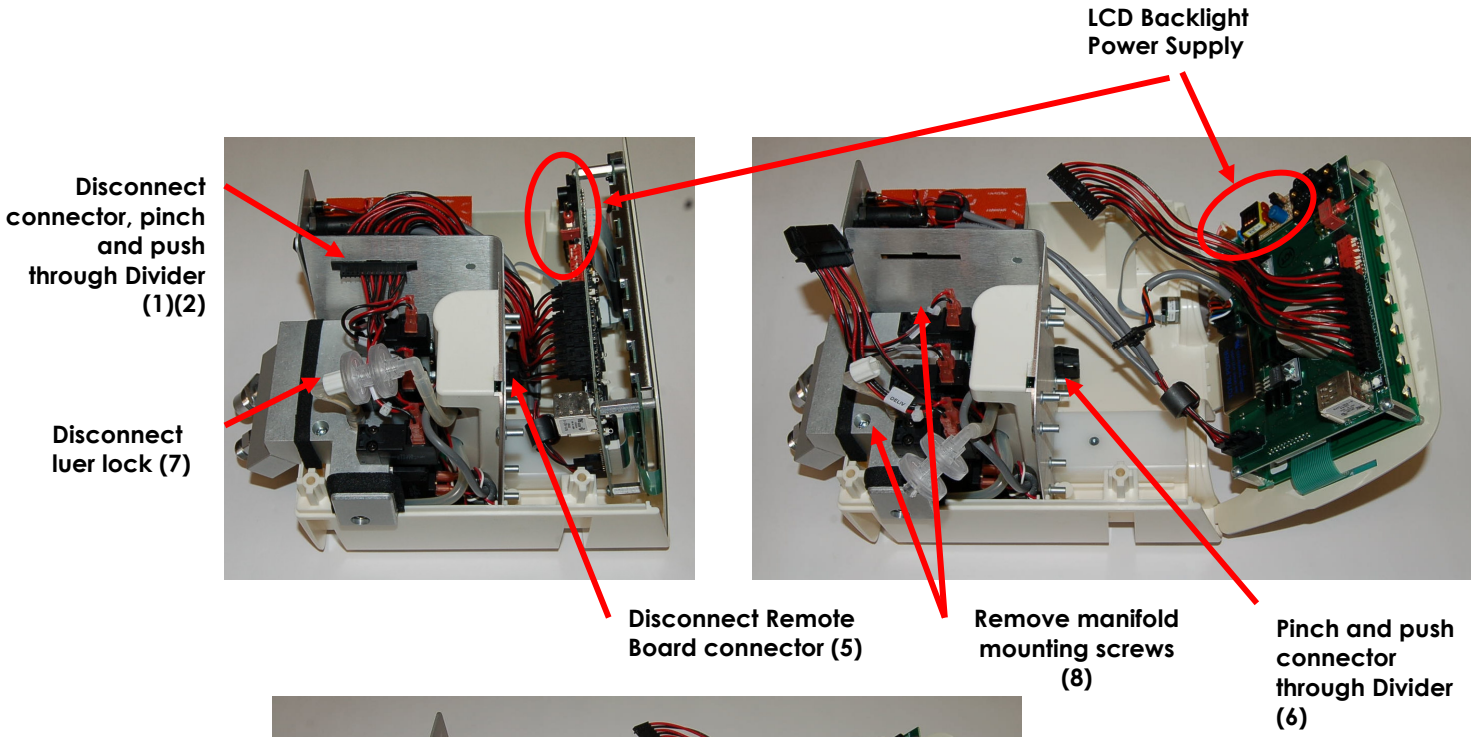
9. Disconnect Oxygen Sensor Cable from CN14 on Remote Sensor Board (PCA-02).
10. Disconnect the silicone tubing on the Divider/Oxygen Sensor Assembly from the barbed fitting on the Bottom Case.

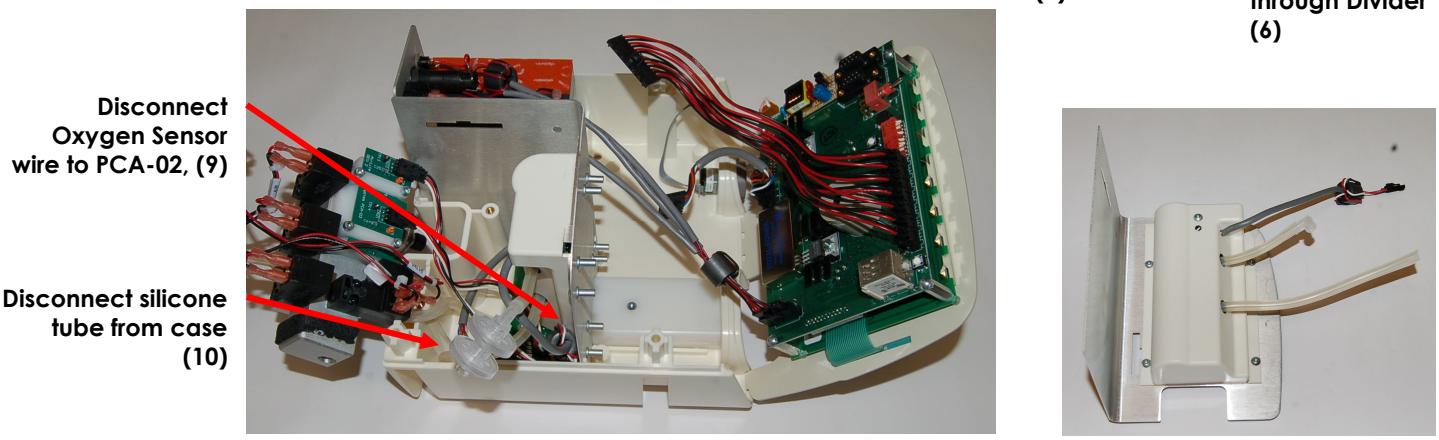
CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

11. Remove the Divider/Oxygen Sensor Assembly from the Bottom Case.


LCD Backlight Power Supply
Disconnect connector, pinch and push through Divider (1)(2)
Disconnect luer lock (7)
Disconnect Remote Board connector (5)
Remove manifold mounting screws (8)
Pinch and push connector through Divider (6)



12.7 Remove the Outlet Fitting Assembly

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

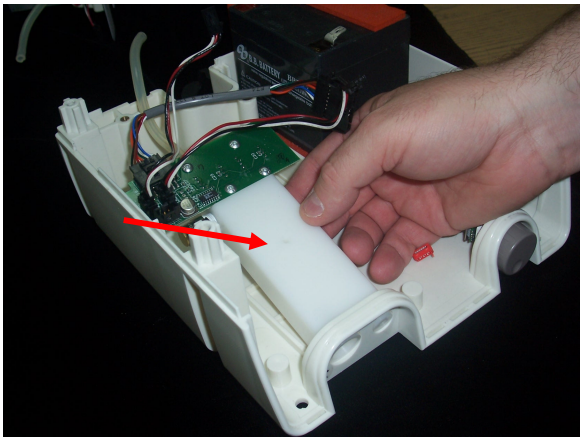
1. Remove Front Panel Assembly, Manifold Assembly, and Divider/Oxygen Sensor Assembly per instructions in sections 12.3, 12.5, and 12.6.
2. Use a T-10 Torx driver to loosen and remove the mounting screw that secures the Outlet Fitting Assembly to the Bottom Case.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

3. Slide the Outlet Fitting Assembly out at an upward angle.
4. Use new cable assemblies if they are provided with the replacement Outlet Fitting Assembly, otherwise utilize the two (2) Inlet Pressure Board Cables (red/white/black cables) and the Remote Board to Bulkhead Cable from the replaced assembly.

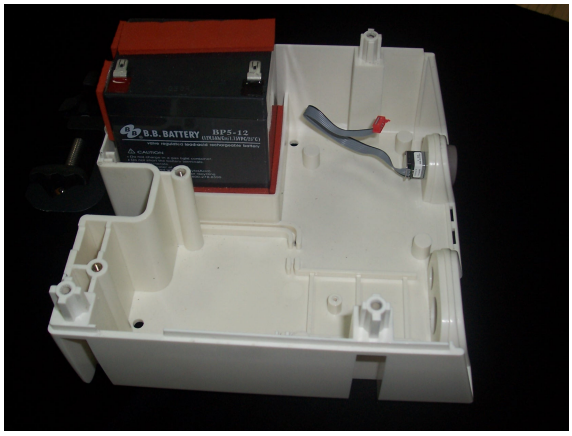


Remove T-10 Torx screw

12.8 Remove the Control Knob/Selector Switch

1. The Control Knob is press-fit. Remove it by simply pulling it off its post (a flat head screwdriver may be required to help loosen knob).
2. Loosen and remove retaining nut and lock washer with 7/16” open-ended wrench.
3. Push the Selector Switch through the Bottom Case mounting hole.

Control Knob, lock washer and nut removed.



Side view of Control Knob/Selector Switch

12.9 Replace the Main Board (PCA-01)

WARNING

The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC Adapter from either the driver or the AC outlet.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

1. Remove Front Panel Assembly per instructions in section 12.3, and place face down on clean work surface.
2. Disconnect the 4-pin connector.
3. Remove four (4) mounting screws using a 5/64” Allen wrench.
4. Tilt the Main Board (PCA-01) up and locate the two (2) ribbon cable connectors. Gently disconnect both cables.

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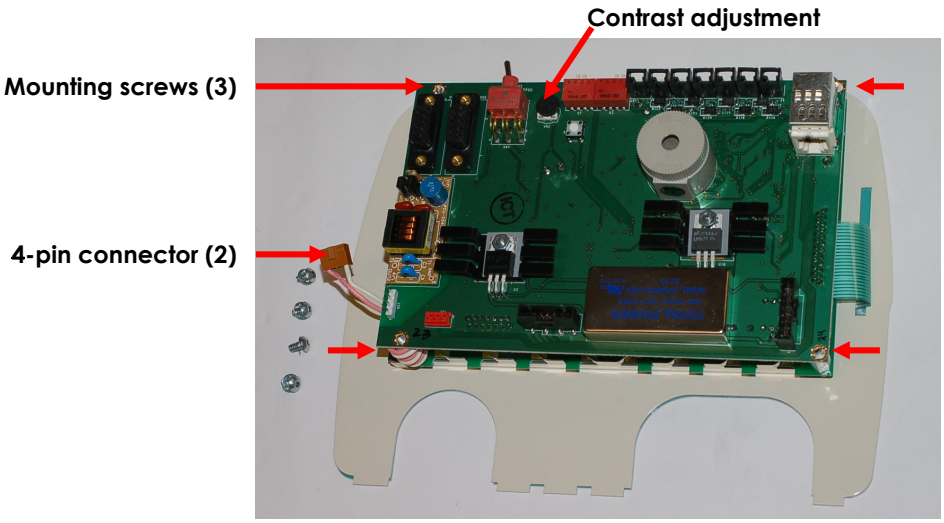
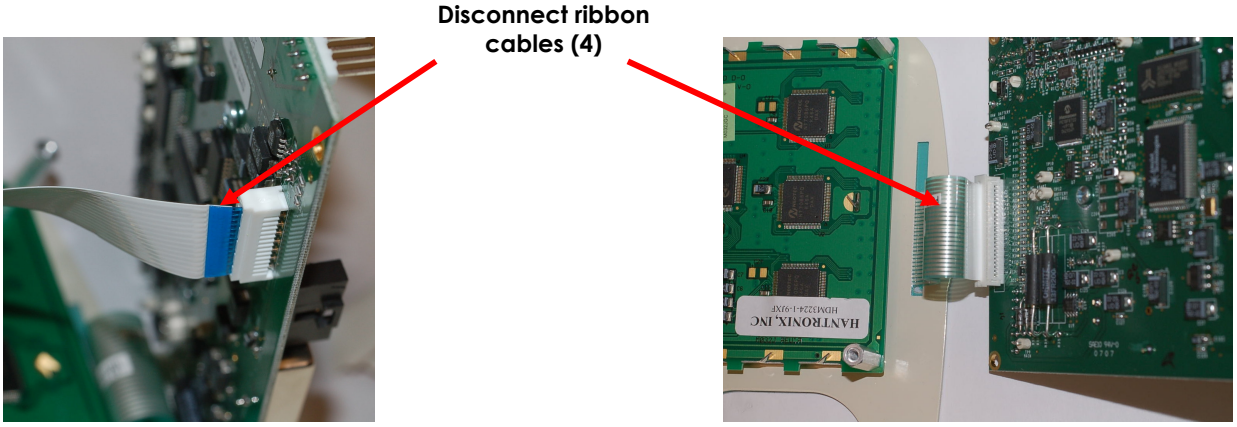
5. To install the new Main Board (PCA-01), reverse the order of the above steps.

6. When installed, the LCD contrast may be adjusted using the contrast adjustment knob on the main PCA board (location noted below).





12.10 Replace the Bottom Case

If the Bottom Case is cracked or broken, it must be replaced. Ensure that the serial number sticker of the nCPAP driver is transferred to the new Bottom Case. The serial number is located on the back of the Bottom Case. See section 13 for rebuild instructions.

The serial number is located on the rear of the nCPAP driver, affixed to the Bottom Case.

13. REASSEMBLING THE NCPAP DRIVER

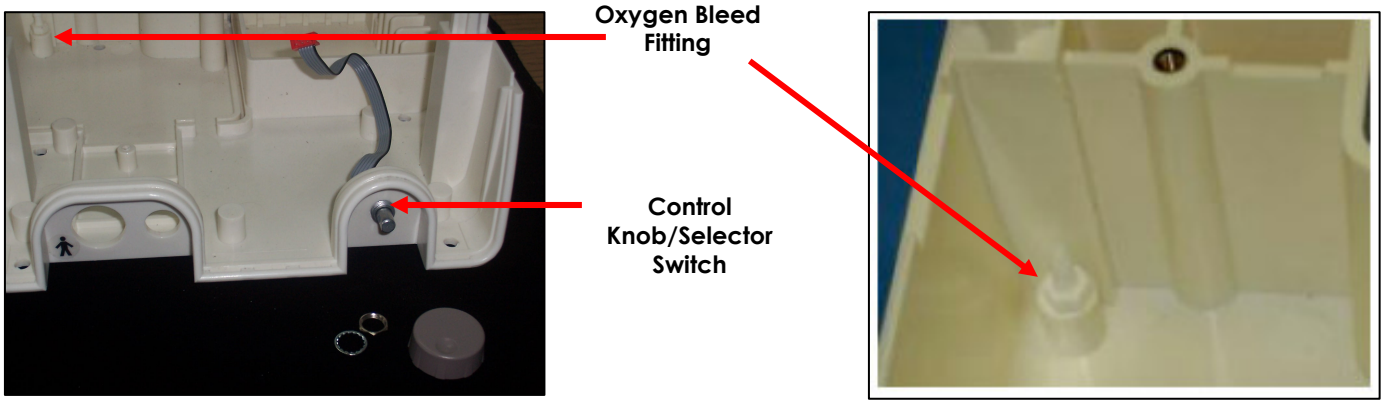
This section provides detailed procedures on replacing components and reassembling the nCPAP driver. These reassembly procedures are provided in order, starting with an empty Bottom Case.

13.1 Assemble the Control Knob/Selector Switch

1. Insert the Selector Switch through the keyway in the Bottom Case. Be sure to align the notch on the switch with the key in the case.
2. Insert the lock washer and the nut. Tighten to 12 in-lbs. using a 7/16" wrench.
3. Position the Control Knob on the post, taking care to align the flats. Press on.

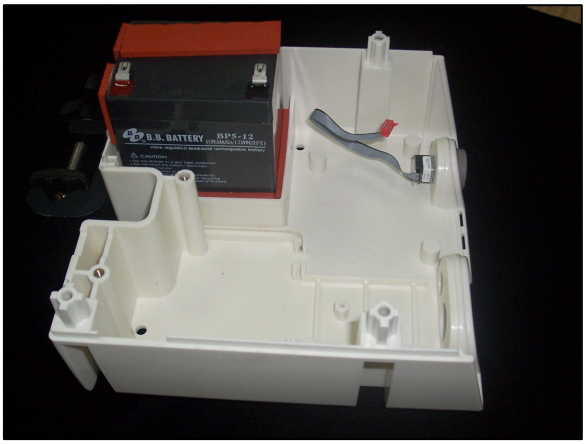
13.2 Install the Oxygen Bleed Fitting

1. Thread Oxygen Bleed Fitting into threaded insert in back left corner of Bottom Case.
2. Torque to 5 in-lb using a 5/16" nut driver.



13.3 Install Battery Assembly

Insert the Battery Assembly into the Bottom Case so that the terminals are closest to the interior of the case.



Properly installed Battery Assembly.

13.4 Install the Outlet Fitting Assembly

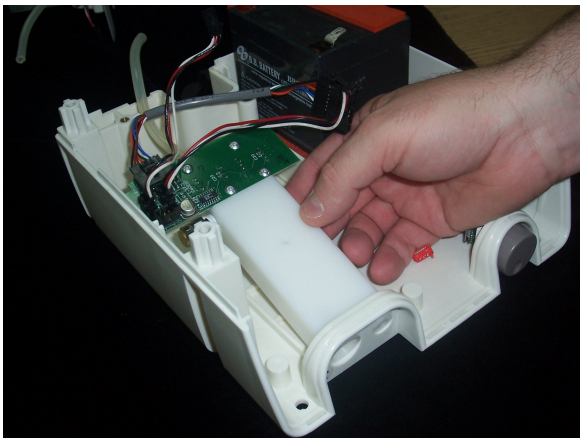
1. Slide the Outlet Fitting Assembly into the Bottom Case at a downward angle.

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

2. Insert the mounting screw into the center of the assembly and turn until the screw head just comes in contact with the Outlet Fitting Assembly, reverse half a turn, and then tighten to a torque of 5 in-lbs using a T-10 Torx driver.



Slide the Outlet Fitting Assembly into the Bottom Case at a downward angle.

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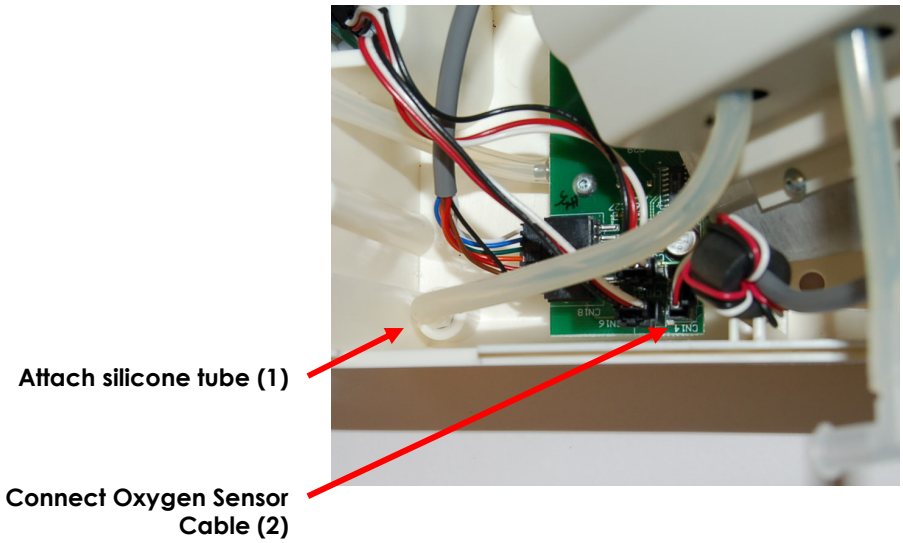
13.5 Install the Divider/Oxygen Sensor Assembly

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

1. Attach the silicone tubing to the fitting on the Bottom Case.
2. Connect the Oxygen Sensor Cable to Remote Sensor Board (PCA-02) at CN14
3. Position the Divider/Oxygen Sensor Assembly into its mounting slots.
4. Gently insert the Remote Board Bulkhead Cable connector through the corresponding slot in the Divider/Oxygen Sensor Assembly.



13.6 Install the Manifold Assembly

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

1. Connect the silicone tubing from the Outlet Fitting Assembly to the barbed fitting on the underside of the Manifold Assembly.
2. Connect the Inlet Pressure Board Cable, connected to the Remote Sensor Board (PCA-02) at connector CN15, to connector CN21 on the Inlet Pressure Board (PCA-03).
3. Connect the Inlet Pressure Board Cable, connected to the Remote Sensor Board (PCA-02) at connector CN16, to connector CN22 on the Inlet Pressure Board (PCA-03).
4. Carefully seat the Manifold Assembly into the Bottom Case without pinching any wires or tubing. BE SURE THAT THE TWO (2) INLET PRESSURE BOARD CABLES ARE NOT PINCHED UNDERNEATH THE MANIFOLD ASSEMBLY OR THE DIVIDER/OXYGEN SENSOR ASSEMBLY.
5. Insert two (2) #8 socket-head screws into the manifold mounting holes and secure to the Bottom Case using a 9/64” Allen wrench. Tighten to a torque of 7 in-lb.
6. Gently insert the Bulkhead to Valves Cable into the corresponding slot in the Divider/Oxygen Sensor Assembly until it locks into place.

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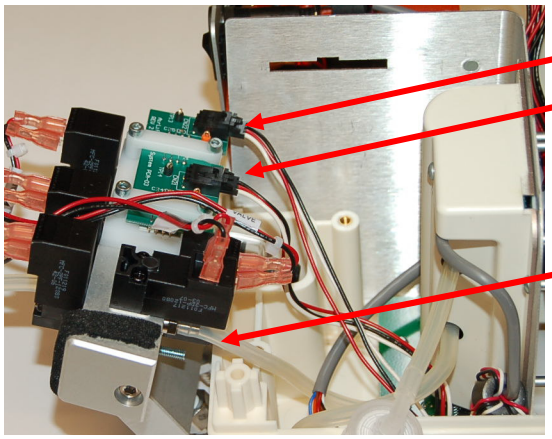
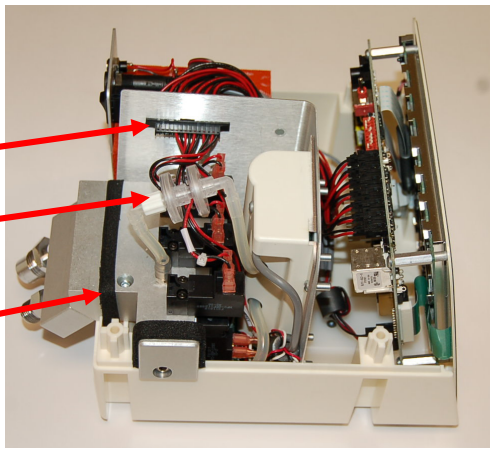
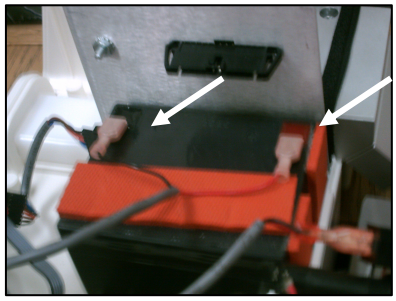
7. Screw the white Luer lock ring to the Oxygen Sensor Filters connected to the Divider/Oxygen Sensor Assembly.
8. Ensure that all joints between the two (2) Oxygen Sensor Filters and the Oxygen Sensor Elbow have remained tight.



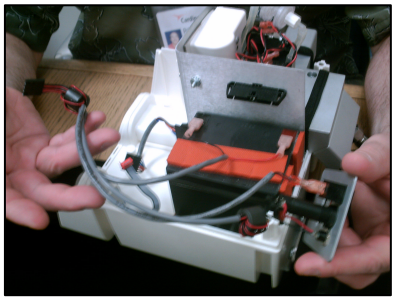

Bulkhead to Valves Connector (6)
Connect luer lock to Oxygen Sensor Filters (7)
Install 2 mounting screws Torque to 7 in-lbs (5)

13.7 Install Power Cable Assembly

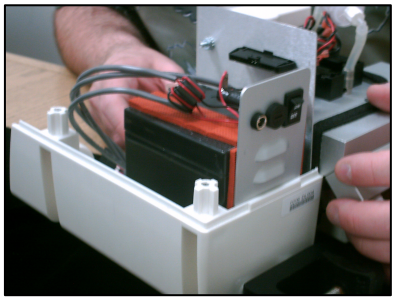
1. Connect the black wire to the negative battery terminal, and the red to positive.
2. Slide the Power Inlet Panel behind the battery, between the ribs in the Bottom Case.



Connect the terminals to the battery (1)



Slide Power Entry Panel behind battery (2)



Properly Installed panel

13.8 Install the Front Panel Assembly

CAUTION

This assembly contains electronic components that are ESD sensitive.

ESD control and handling measures should be followed while performing this process.

1. Verify that the Valve Drive Cable is correctly connected to the Main Board (PCA-01).

   1.1. Locate the red and black wires connected to pins 1 and 2 respectively of the large black fourteen (14) pin connector that will connect to the Bulkhead to Valves Cable already attached to the Divider/Oxygen Sensor Assembly. Pin 1 is identified by a triangle etched into the bottom surface of the fourteen (14) pin connector.

   1.2. The red and black wires should be connected to connector J27 (labeled **SPARE VALVE 2**) on the Main Board (PCA-01).

   1.3. The wires should be connected according to the following wiring schedule:

14 Pin Connector Pin #s	Main Board (PCA-01) Connector
1 and 2	J27 (labeled **SPARE VALVE 2**)
3 and 4	J26 (labeled **SPARE VALVE 1**)
5 and 6	J8 (labeled **CALIB**)
7 and 8	J7 (labeled **VENT**)
9 and 10	J6 (labeled **DELIVERY**)
11 and 12	J5 (labeled **AIR**)
13 and 14	J4 (labeled **O2**)

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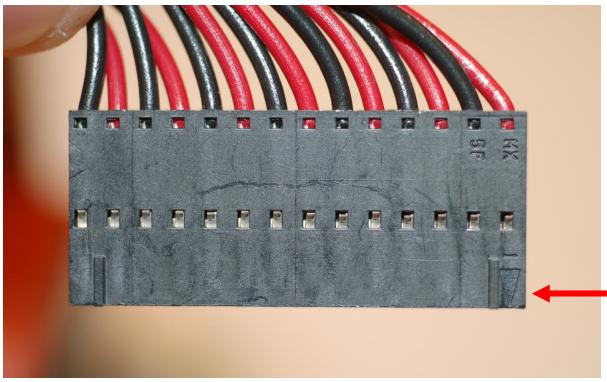
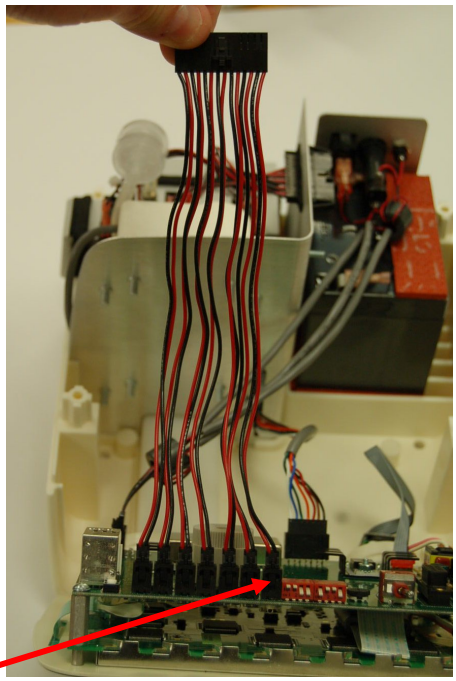
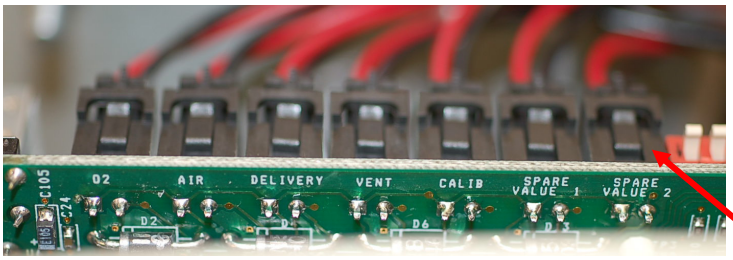


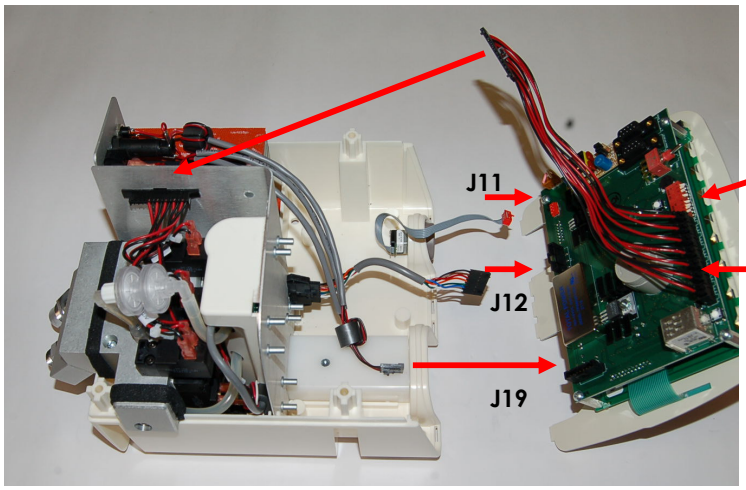
Pin 1
(on underside)

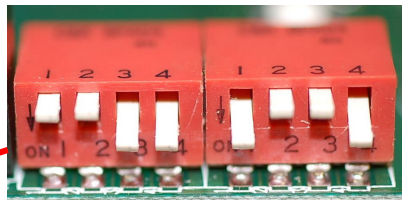




J27
(Spare Valve 2)

2. Plug the Control Knob/Selector Switch into connector J11.
3. Plug the Main to Bulkhead cable into connector J12.
4. Plug the Power Cable Assembly into connector J19.
5. Align the Front Panel tabs into the slots in the Bottom Case.
6. Tilt the front panel back, taking care to tuck the wiring above or below the standoffs on the Divider/Oxygen Sensor Assembly.
7. Plug the Valve Drive Cable into the Bulkhead to Valves Cable.
8. Verify and/or set the dipswitch configuration for normal operation:





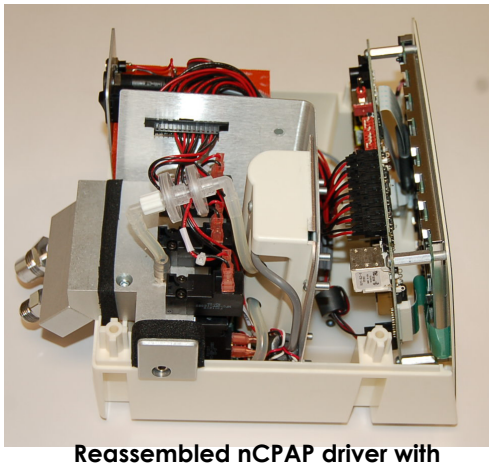
Verify dip switch configuration

Verify cable connections

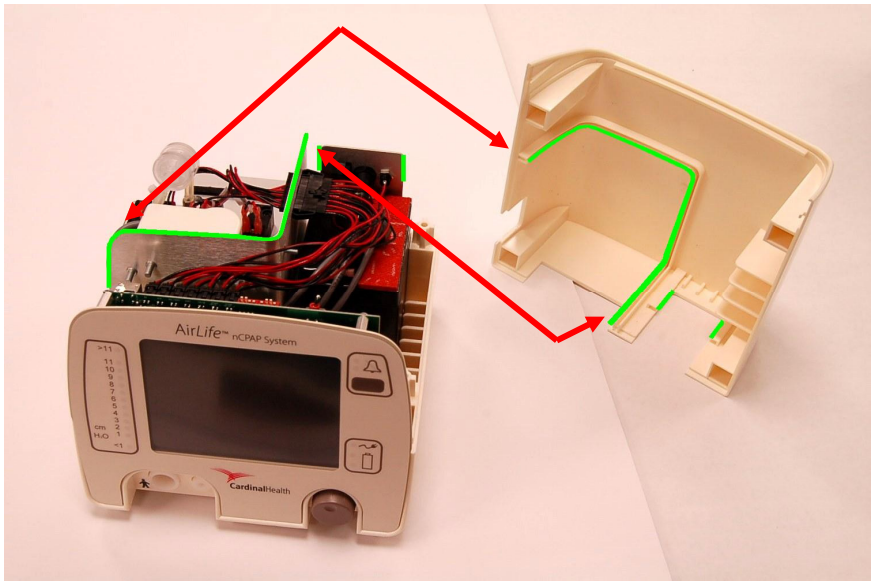
Note: Do not replace the Top Case until the Power-On Self Test is complete and the Patient Treatment Mode Screen (the main screen) appears.

13.9 Install the Top Case

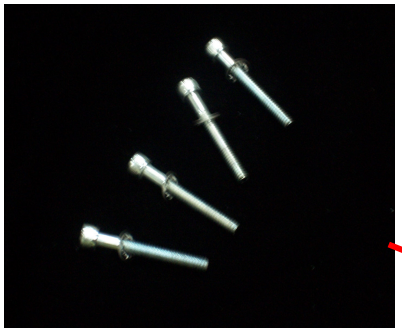
1. When replacing the Top Case, verify that all assemblies inside the driver are secure. Check that all connectors are fully latched and all luer fitting connections are snug.
2. Gently place the Top Case on top of the Bottom Case, ensuring that all cables and hoses are not pinched or kinked.
3. Looking from the front of the driver, ensure all metal panels slide into their respective slots in the Top Case. Lower the Top Case until it's fully seated on the Bottom Case.
4. Turn the unit upside down.
5. Insert the four (4) #8 screws into the mounting holes and secure using a 9/64" Allen wrench. Torque to 5 in-lbs.

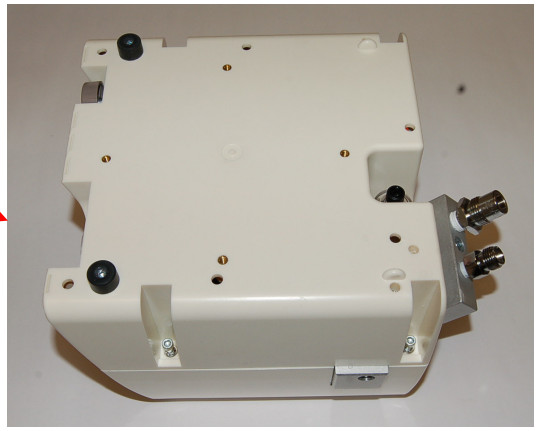


Reassembled nCPAP driver with Top Case removed.



Align metal panels with slots in Top Case





Invert unit, install mounting screws

13.10 Charging the Battery after Maintenance

After any maintenance is performed, it is recommended that the unit be plugged into facility power for a minimum of 16 hours to allow the battery to fully charge before the driver is put into service.

The battery will charge when the unit is powered off and plugged into a wall socket.

13.11 Disposal Recommendations

The battery and LCD display must be disposed of according to local regulations.

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14. AirLife™ nCPAP Driver Comprehensive Performance Test: Model Number 006900

The following test must be conducted annually and after any service/ repair in order to ensure that the device is operating within its specified limits. It is prudent to maintain records of the Comprehensive Performance Tests and Preventative Maintenance. Each device has a unique serial number printed on the rear face of the housing for tracking purposes.

14.1 Comprehensive Performance Test

Test Set-up Notes:

1. The Air and Oxygen supply lines must be no longer than 15 feet in length.

2. Use calibrated test equipment with appropriate accuracy and tolerances to verify the device outputs. As noted below and on the data sheet, the accuracy and tolerance of the test equipment must be considered when determining if a response is within the stated acceptable limits. Standardize all test equipment to the manufacturer's recommended procedure before collecting data.

   - Note: Galvanic oxygen sensors are affected by pressure. Galvanic sensors must be standardized (calibrated) at the same pressure the FiO_2 measurement will be taken. If the galvanic sensor is placed in the pressurized portion of the circuit, it must be re-standardized with every change in CPAP level to ensure accuracy.

3. The Driver has an internal timer that starts when the single audible beep is activated immediately after power up. Use an external timer initiated concurrently with the audible beep in order to plan for the automatic oxygen calibration routines that occur. The driver performs a 2 point oxygen calibration during the initial self-test to capture FiO_2 values for 21% and 100% oxygen. It also performs oxygen calibration routines at elapsed times of 20 minutes and 40 minutes to correct for the electronics warming up. The FiO_2 accuracy will remain within the stated accuracy during the warm-up period if the automatic calibration routines are allowed to occur as scheduled. Note that the device will automatically abort and postpone a scheduled calibration sequence if an alarm is active or if a parameter is changed during a calibration routine. Plan around the calibration routines or allow the device to warm-up for at least 40 minutes before completing the tests to ensure optimal FiO_2 accuracy.

4. If using tanks for air or oxygen sources, then ensure that the pressure is adequate to complete the test (preferably a minimum of 800 PSI) and regulated between 41-66 PSI, preferably at a nominal of 50 ± 3 PSI.

Start-Up, Splash Screen, and Unit Inspection:

5. Record the serial number of the Airlife Driver and the pertinent information for all test equipment used to verify the performance of the device.

6. Visually inspect the inlet air filter and filter bowl. If the filter is dirty or wet, it should be replaced.

7. Connect the Device to a clean, dry Air and oxygen source regulated between 41-66 PSI, preferably at a nominal of 50 ± 3 PSI.

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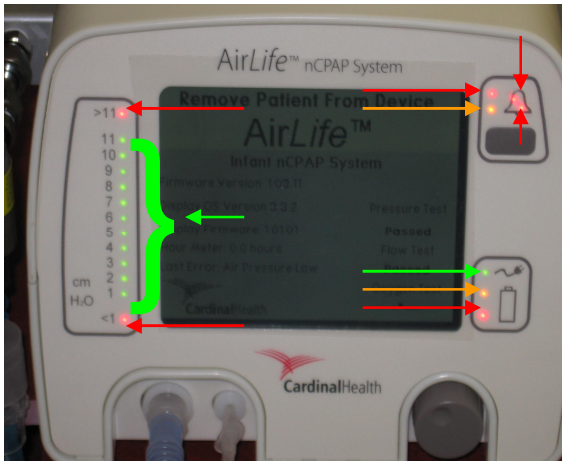
8. Plug the power supply into the receptacle on the rear face of the driver and the power chord into a properly grounded AC receptacle.

9. Connect an approved patient circuit to the Driver (e.g. RT132 or RC51-12002)

10. Connect an approved generator (e.g. Catalog Number 006905) to the patient circuit and install a MEDIUM set of prongs (e.g. Catalog Number 006915 included in the generator kit).

11. Turn the power switch to the ON position and monitor the splash screen. Record the following information from the Splash Screen:
    - Firmware Version
    - Display OS
    - Display Firmware
    - Hour Meter display
    - Verify that all LEDs are illuminated and the correct color (see Figure)
    - Circle PASS or FAIL.

12. The Power-On Self test will take 45 seconds. If it successfully passes the self-test, then the device will enter patient treatment mode, as indicated by the Splash Screen being replaced with the Main Screen and flow exiting the patient outlet port. During the power-on self test, the device automatically performs the following actions and displays PASS or FAIL. Record the results of the tests by circling PASS or FAIL on the data sheet:



    - Checks the Patient Pressure Sensor zero point
    - Checks the Patient Flow Sensor zero point
    - Flushes the oxygen and air lines
    - Performs a 2 point O_2 calibration

    Note: If an error occurs during the power-on self-test, the Driver will not enter Patient Treatment Mode and the main screen will be replaced with an error screen. Consult the troubleshooting section for further details and recommended actions.

13. Verify that the following default *Set* values are on the main screen:

    - CPAP Set: 5 cm H_2O
    - % O_2 Set: 21% O_2 and Highlighted
    - Flow Rate Target: 8 LPM (actual flow may vary based on generator brand, leaks, etc)
    - Circle PASS or FAIL.

14. Use an appropriate clip to seal the MEDIUM prongs completely and allow the device to stabilize at the default settings.

    - Note: The Device automatically enters a 2 minute grace period to allow for patient set-up. This is indicated by the “mute” LEDs being illuminated. Exit the grace period by pressing the alarm clear/mute button before proceeding (or allow the unit to time-out after 120 seconds)

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15. With the power supply connected, verify that the battery charging lightning bolt icon is illuminated, the green battery LED is lit, the "plug" icon is displayed, and the word "Charge" is displayed. Circle PASS or FAIL

16. Unplug the external power and verify that a single audible alarm (beep) occurs and the lightning bolt in the battery icon is replaced with bars indicating the percent charge remaining. Circle PASS or FAIL

17. Reconnect external power to unit.

Bleed Flow Measurement: A minimum bleed flow is essential for accurate and responsive FiO_2 blending

18. Connect tubing to the bleed flow outlet port located on the bottom housing of the Driver (See figure in section 3). Do not occlude the bleed flow port as this may damage the oxygen sensor within the Driver.

19. Normal Bleed flow specifications for inlet pressures at 50 ± 1 psi is 0.9 to 2.7 LPM with a circuit and generator connected.

    - To allow for normal variations in inlet source pressure of 41- 66 PSI (and potentially the unavailability of a breathing circuit and generator), the acceptable bleed flow specification is 0.7 – 3.0 LPM.
    - If the bleed flow falls outside of the range stated, then check the plumbing inside the Driver for loose connections and/or kinks in the tubing and re-test the bleed flow.

20. If the bleed flow falls within specification, circle "PASS". If the bleed flow is not within the stated specification, then circle "FAIL" and remove the Driver from service.

21. Turn the main power switch off and confirm that the bleed flow drops to zero

FiO_2 Blender Performance: This test is performed to ensure accuracy of the delivered FiO_2.

    - Note: The Driver utilizes a long-life, ultrasonic O_2 sensor that is automatically calibrated at start-up, at 20 minutes, 40 minutes (to compensate for warm-up), and every 12 hours thereafter.

22. Set the FiO_2 to 21% and allow the system to equilibrate for 60 seconds (to allow for the normal 20 second grace period and the response time of the external O_2 sensor).

23. Record the $\%0_2$ reading on the Driver's LCD screen. The value must be within +/- 3% of the FiO_2 set point.

24. Record the % O_2 as read by an independent Oxygen Analyzer.

25. Repeat for FiO_2 settings of 30%, 50%, 70% and 100%.

26. The value must be within the Driver's stated accuracy (+/- 3 percentage points) PLUS the accuracy of the analyzer being used to collect the data (the accuracies are cumulative and must be included/added to properly disposition the results).

27. Record PASS if all values are within the stated accuracy or FAIL if the results fall outside the stated accuracy. If the FiO_2 readings fall outside of the stated range, check the following:

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- If within the 40 minute warm-up period, allow the driver to complete the scheduled calibration routines and re-test.
- Ensure that the independent O_2 sensor has been calibrated properly (and at the same pressure that the measurement is taken). Set the FiO_2 to 21% and/or 100% and evaluate the results displayed by the independent sensor. Note that the Driver is designed to only deliver Air when set to 21% and only pure Oxygen when set to 100%.

CPAP and Flow Rate Accuracy: This test is performed to ensure accuracy of the delivered CPAP level and the flow rate exiting the Driver.

28. Set the Driver CPAP level to 5 cm H_2O and allow approximately 60 seconds for the valves to stabilize.

29. Record the pressure readings from the Driver's LED bar graph, Driver LCD, and from an appropriate independent Manometer.

30. Verify that each reading is within ± 1 cm H_2O of the Driver's Set Value.

31. If all values are within the stated tolerance, then circle PASS. Otherwise circle FAIL.

32. Record the flow rate as measured by the Driver (on LCD display) and by an independent flow meter.

33. Verify that the flow rate measured by the Driver on the LCD display is within +/- 2 lpm of the flow measured by the independent flow meter. The accuracy of the independent flow meter must be considered by adding its measurement tolerance to the stated accuracy of the Driver in order to properly disposition the results. Note: the "Target" flow is only a reference point for the device and does not need to be calibrated.

34. If all values are within the stated tolerance, then circle PASS. Otherwise circle FAIL.

35. Repeat for CPAP settings of 3 and 8 cm H_2O.

36. If CPAP levels fall below specification, ensure that the prongs are occluded and all connections on the circuit, generator, and prongs are secure and leak free.

Low Source Pressure Alarm Tests: This test verifies that the source gas inlet pressure sensors and alarm modes are operational.

37. Set the FiO_2 to 60% and allow ~ 60 seconds for the valves to adjust.

38. Disconnect the air source.

39. Verify an audible alarm occurs (High priority, red flashing).

40. Verify that 'Air Pressure Low' appears in the message bar (alternating between low air pressure and high FiO_2). Note that in the absence of air (or when the Driver detects a low air source pressure), the Driver automatically switches to oxygen only.

41. Verify that CPAP pressure is maintained utilizing the oxygen source. Note that the FiO_2 will be 100% and the High FiO_2 alarm will be active.

42. Re-connect the Air source and allow at least 60 seconds for the valves to adjust and re-stabilize.

    - Verify that the system returns to the original FiO_2 setting

43. Press the Alarm/Mute button to clear the latched alarm. Do not proceed until the alarms clear and the system has re-stabilized.

44. Disconnect the Oxygen source.

45. Verify an audible alarm occurs (High priority, red flashing).

46. Verify that 'Oxygen Pressure Low' appears in the message bar (alternating between low oxygen pressure and low FiO_2).

47. Verify that CPAP pressure is maintained utilizing the air source. Note that the FiO_2 will be 21% and the Low FiO_2 alarm will be active.

48. Re-connect the Oxygen source and allow at least 60 seconds for the system to re-stabilize.

49. Verify that the system returns to the original FiO_2 setting.

50. Press the Alarm/Mute button to clear alarm.

51. If all alarm conditions were met and the auto-recovery returned the system to original condition, then circle PASS. Otherwise circle FAIL.

Low Pressure/ Disconnect Alarm Test:

52. Occlude both prongs and set CPAP to 5 cm H_2O. Allow valves to stabilize for at least 60 seconds. FiO_2 may be set to 21% for this test.

53. Remove the occlusion of the prongs (or remove the prongs from the generator).

54. Verify that a medium priority audible alarm is actived (yellow flashing LED) and 'Disconnect' or "Low Pressure" alarm text appears in the message bar within 15 seconds (normal alarm delay).

55. Verify that the flow rate displayed by the Driver is at "Target" flow +/- 3 lpm.

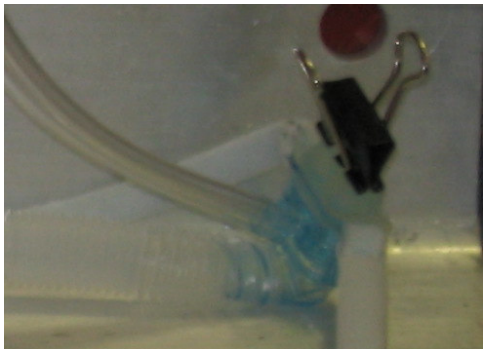
56. If the Low Pressure/ Disconnect alarm activated within 15 seconds, then circle PASS. If this test fails, verify that both prongs are open. If no alarm occurs, then circle FAIL.

High Pressure Alarm Test:

57. Completely remove the white exhaust tubing from the generator's exhaust Port.

58. Occlude the prongs and set CPAP to 5 cm H_2O. Allow valves to stabilize for approximately 60 seconds.

59. Completely occlude the exhaust port momentarily and then release the occlusion.



60. Verify that a 'High Pressure' alarm actives immediately (no alarm delay) and that the CPAP pressure and flow go to zero (normal response as the Driver stops flow and vents the system).

61. After the system settles, flow will re-initiate and the driver will attempt to resume normal operation.

62. If the alarm activates immediately and then recovers, then circle PASS, otherwise circle FAIL.

63. Press the Alarm Mute/Clear button to clear the latched High Pressure alarm.

64. Place exhaust tubing back onto the exhaust port.

Mechanical High Pressure Relief:

65. With the Driver turned on and set to CPAP of 5 cmH_20 and FiO_2 of 21%, disconnect the Generator and Circuit from the Driver and attach a high range manometer to the patient outlet port to occlude the Circuit Driveline and measure the internal pressure.
    Note: The manometer must be capable of measuring at least 250 cmH_2O

66. Record and verify that the pop-off pressure on the manometer is within the specifications noted on the data sheet.

67. Record PASS or FAIL

Battery Tests:

68. The charging system for the internal battery is operational whenever AC power is supplied to the Driver (regardless of whether it is turned on or off). The battery requires approximately 14 hours to fully charge from a depleted state.

69. From a full charge, the Driver should operate for 4 hours (including the duration of time that the low battery alarm is active). Operate the Driver under nominal conditions (i.e. CPAP of 5) while under battery power and monitor the duration of operation (inclusive of the low battery alarms). As the battery level drops to low levels, a series of low battery alarms should activate. Note if the alarms activate and the total duration that the Driver operates while on battery power (inclusive of the alarm periods).

    - Note: The expected battery life is 2 years and must be replaced every 2 years. If the battery has been in service for more than 2 years or fails to operate for the stated duration, the battery must be replaced.

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14.2 Performance Test Data Sheet

Airlife nCPAP Driver Performance Test Data Sheet					
Driver Serial Number:			**Equipment ID:**		
Test Equipment:	ID# / Calibration Due Date	Tolerance	Test Equipment:	ID# / Calibration Due Date	Tolerance
Manometer			O2 Analyzer		
Flowmeter			Stop Watch		
Date:			Last Performance Test Date:		
Reason for Test:			Hour meter at last test:		
Splash Screen Information:			Splash Screen Inspection:		
Firmware Version			LEDs Illuminated and correct color	PASS	FAIL
Display OS Version			Passes Pressure Test	PASS	FAIL
Display Firmware			Passes Flow Test	PASS	FAIL
Hour Meter Reading			Passes Oxygen Calibration & Test	PASS	FAIL

Unit Inspection	**Test Criteria**						**Results**	
Air Filter & Filter Bowl	Visually Clean		Soiled		Wet		PASS	FAIL
Default Set Values	CPAP = 5, FiO_2 = 21%, Flow Target = 8 lpm						PASS	FAIL
Battery Charging	Lightning bolt icon present in battery icon, Plug icon illuminated Green LED at plug decal illuminated, "Charge" displayed						PASS	FAIL
Power Loss Notification	Single Audible Beep, Battery Percentage displayed						PASS	FAIL
Bleed Flow Inspection	**Measured Flow (lpm)**		**Acceptance Criteria**				**Results**	
Bleed Flow Rate			0.7-3.0 LPM				PASS	FAIL

Blender Accuracy
(FiO_2 delivered thru Patient Circuit Outlet Port with set & actual CPAP = 5 cmH_20 with Cardinal accessories attached)

FiO_2 Set Point	21%	30%	50%	70%	100%	Results	
Driver % 0_2 Reading on LCD						PASS	FAIL
Acceptance Criteria	± 3 % 0_2	± 3 % 0_2	± 3 % 0_2	± 3 % 0_2	± 3 % 0_2	Note: allow ~ 60 sec settling time (normal 20 sec grace period + external sensor response time)	
External O_2 Analyzer % 0_2 Reading						PASS	FAIL
Acceptance Criteria	± (3 + external sensor accuracy rating) % 0_2	± (3 + external sensor accuracy rating) % 0_2	± (3 + external sensor accuracy rating) % 0_2	± (3 + external sensor accuracy rating) % 0_2	± (3 + external sensor accuracy rating) % 0_2	Note: The Driver's stated tolerance is ± 3%. The accuracy/tolerance of the sensor being used to verify the reading must be considered (added) for this pass/fail criteria	

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CPAP and Flow Rate Accuracy:					
CPAP SetPoint	3 cmH_20	5 cmH_20	8 cmH_20	Results	
Driver LCD Display				PASS	FAIL
Driver LED Illuminated				PASS	FAIL
Independent Pressure Sensor				PASS	FAIL
Acceptance Criteria	3 ± 1 cmH_20 5 ± 1 cmH_20 8 ± 1 cmH_20 Note: The Driver's stated tolerance is within ± 1 cmH_20. The accuracy of the sensor used to verify the reading must be considered (added) for this pass/fail criteria				
Flow Rate Displayed on LCD				PASS	FAIL
Flow Rate by Independent Sensor					
Acceptance Criteria	Flow Rate Displayed on LCD must be within ± 2 LPM of the independent sensor. This value is based on the Driver's stated tolerance of 1.5 LPM rounded to 2 LPM to account for the Displayed accuracy. Note: The accuracy of the sensor used to verify the reading must be considered (added) for this pass/fail criteria				

Low Source Pressure Alarms	**Alarm Confirmation/ Data**	**Successful Auto-Recovery**	**Results**	
Low Air Inlet Pressure	Audible Alarm Activated, High Priority/Red LED, Message Bar Confirmation, Air Pressure Low	Returned to Set FiO_2 Audible Alarm cleared	PASS	FAIL
Low 0_2 Inlet Pressure	Audible Alarm Activated, High Priority/Red LED, Message Bar Confirmation, O_2 Pressure Low	Returned to Set FiO_2 Audible Alarm cleared	PASS	FAIL

Low Pressure/ Disconnect Alarm	**Alarm Confirmation/ Data**	**Criteria**	**Results**	
Alarm Confirmation	Audible, LED, MB Text	Audible & Visual (LED & Text) Alarm	PASS	FAIL
Flow Rate after Disconnect		Target ± 3 LPM	PASS	FAIL
High Pressure Alarm	**Alarm Confirmation/ Data**	**Criteria**	**Results**	
Occluded Exhaust	Audible & Visual (LED & Text) Alarm	Flow & Pressure to 0	PASS	FAIL

Mechanical Pop-Off	**Data**	**Criteria**	**Results**	
Measured dead-head pressure		211 ± 22 cmH_20	PASS	FAIL

Battery Test	**Data**	**Criteria**	**Results**	
Low battery alarms activate		Yes or No	PASS	FAIL
Run time on Battery		4 hours (inclusive of alarm periods)	PASS	FAIL

Results of Performance Test:		
Test Disposition	**PASS or FAIL (Circle One)**	**Signature/ Date:**

15. TROUBLESHOOTING

The following section contains tables that define the Alarm and Warning Conditions that may be encountered.

15.1 Alarm Details and Actions

The following table defines the potential Alarms that may appear during the Power-On Self Test and during Patient Treatment Mode (the main screen). The alarm description, priority (low, medium, high), alarm indicators and suggested action to most likely remedy the condition are also included.

Alarm	Priority	Indication	Suggested Action
Elevated Pressure (2 cm H_2O over Set Value)	Medium	• Audible alarm • Yellow flashing Warning LED • Message Bar	• Check the exhaust tube for occlusions or restrictions
Low Pressure (2 cm H_2O under Set Value)	Medium	• Audible alarm • Yellow flashing Warning LED • Message Bar	• Check for leaks in the tubes and circuit, or in the nasal prongs and mask • Check supply gases
High Pressure (≥12 cm H_2O for 2 seconds or ≥18 cm H_2O instantaneously)	High	• Audible alarm • Red flashing Fault LED • Message Bar • The patient delivery valve closes and a relief valve opens immediately upon alarm. System attempts to reinitiate treatment every three (3) seconds until the alarm condition clears.	• Check the exhaust tube for occlusions or restrictions
Disconnect (Table Based)	Medium	• Audible alarm • Yellow flashing Warning LED • Message Bar • The flow rate is adjusted to Target Flow ± 2 lpm.	• Check for leaks or disconnections in the tubes and circuit, or in the nasal prongs and mask.
% O_2 Alarms (Utilizes an oxygen time product. Time product is defined as: the variance outside of this FiO_2 range multiplied by the duration of the variance.)	Medium	• Audible alarm • Yellow flashing Warning LED • Message Bar says "FiO_2 Limit"	• Check Supply Gases • Restart driver to perform oxygen sensor calibration
	High	• Audible alarm • Red flashing Fault LED • Message Bar says "FiO_2 Warning"	• Check supply gases • Restart driver to perform oxygen sensor calibration

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Alarm	Priority	Indication	Suggested Action
Leak (3 lpm over the Target Flow rate or a Flow Rate of > 15 lpm)	Medium	• Audible alarm • Yellow flashing Warning LED • Message Bar	• Check for leaks or disconnections in the tubes and circuit, or in the nasal prongs and mask • If leak cannot be corrected by re-positioning or re-sizing the patient interface, the Target flow can be increased to allow the driver to deliver higher flows when necessary.
Low Flow (≤ 3 lpm flow rate)	High	• Audible alarm • Red flashing Fault LED • Message Bar	• Check the exhaust tube for occlusions or restrictions
External Power Disconnect	Not an alarm Notification only	• Single audible burst • Indicator on display • Green Power LED turns off	• Plug in the AC Adaptor
Battery Low Dual Stage Alarm	Medium (~24 minutes remaining)	• Audible alarm • Yellow flashing Warning LED • Yellow Power LED	• Plug in the AC Adaptor
Battery Low Dual Stage Alarm	High (~12 minutes remaining)	• Audible alarm • Red flashing Fault LED • Message Bar • Red Power LED	• Plug in the AC Adaptor
Battery Charge Fault	High	• Audible alarm • Red flashing Fault LED • Message Bar • Red Power LED • LCD indicator	• System will be required to have the AC Adaptor connected to ensure patient treatment is not interrupted.
Oxygen Pressure Low	High	• Audible alarm • Red flashing Fault LED • Message Bar	• Correct oxygen supply pressure • Follow on-screen directions • Select ‘Air Only’ mode
Oxygen Pressure High	High	• Audible alarm • Red flashing Fault LED • Message Bar	• Correct oxygen supply pressure • Follow on-screen directions • Select ‘Air Only’ mode
Air Pressure Low	High	• Audible alarm • Red flashing Fault LED • Message Bar	• Correct air supply pressure • Follow on-screen directions • Turn Select Knob, ‘Oxygen Only’ mode may be selected to clear alarm
Air Pressure High	High	• Audible alarm • Red flashing Fault LED • Message Bar	• Correct air supply pressure • Follow on-screen directions • Turn Select Knob, ‘Oxygen Only’ mode may be selected to clear alarm
Oxygen Sensor Calibration Error	High	• Audible alarm • Red flashing Fault LED • Oxygen Calibration Error Warning Screen	• Follow on-screen directions • While alarm is active, the driver provides CPAP and FiO_2; however, the FiO_2 may not be accurate. • Remove patient from device and restart driver

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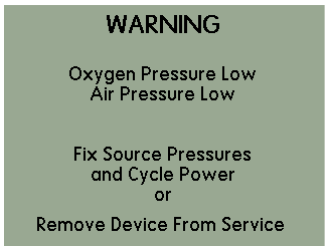
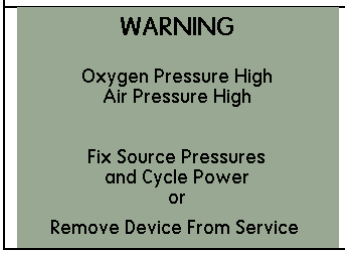
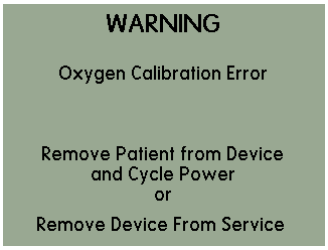
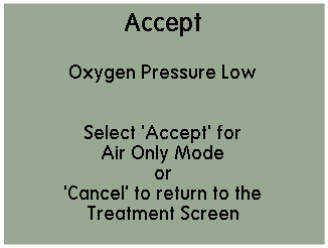
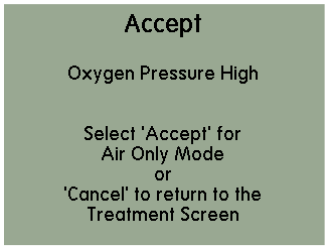
Alarm	Priority	Indication	Suggested Action
Flow/Pressure Sensor Failure	Not an alarm Notification only	• Audible alarm • Yellow flashing Warning LED • Sensor Calibration Failure Warning Screen	• Make sure patient is disconnected from circuit and restart driver. • Follow on-screen directions
Non-Fatal Software Fault	High	• Audible alarm • Red flashing Fault LED • Message Bar	• Record the Fault code • Follow on-screen directions
Fatal Software Fault	High	• Continuous Audible alarm • Red Fault LED • Warning Screen	• Driver will cease operation • No Patient flow • Remove Patient from driver • Record the Fault code • Follow on-screen directions • Remove driver from service

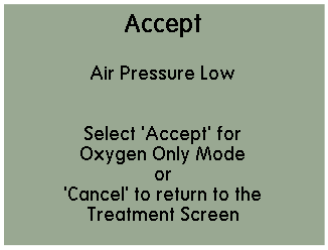
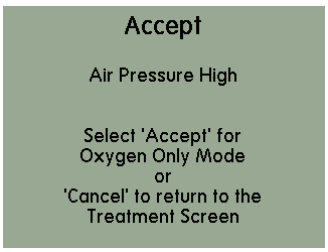
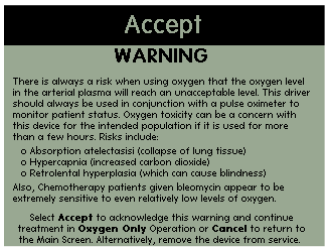
15.2 Warning Screens

The following table defines the potential Warning Screens that may appear during the Power-On Self Test and during Patient Treatment Mode (the main screen). The most likely fault modes and potential actions to remedy the condition are also included.

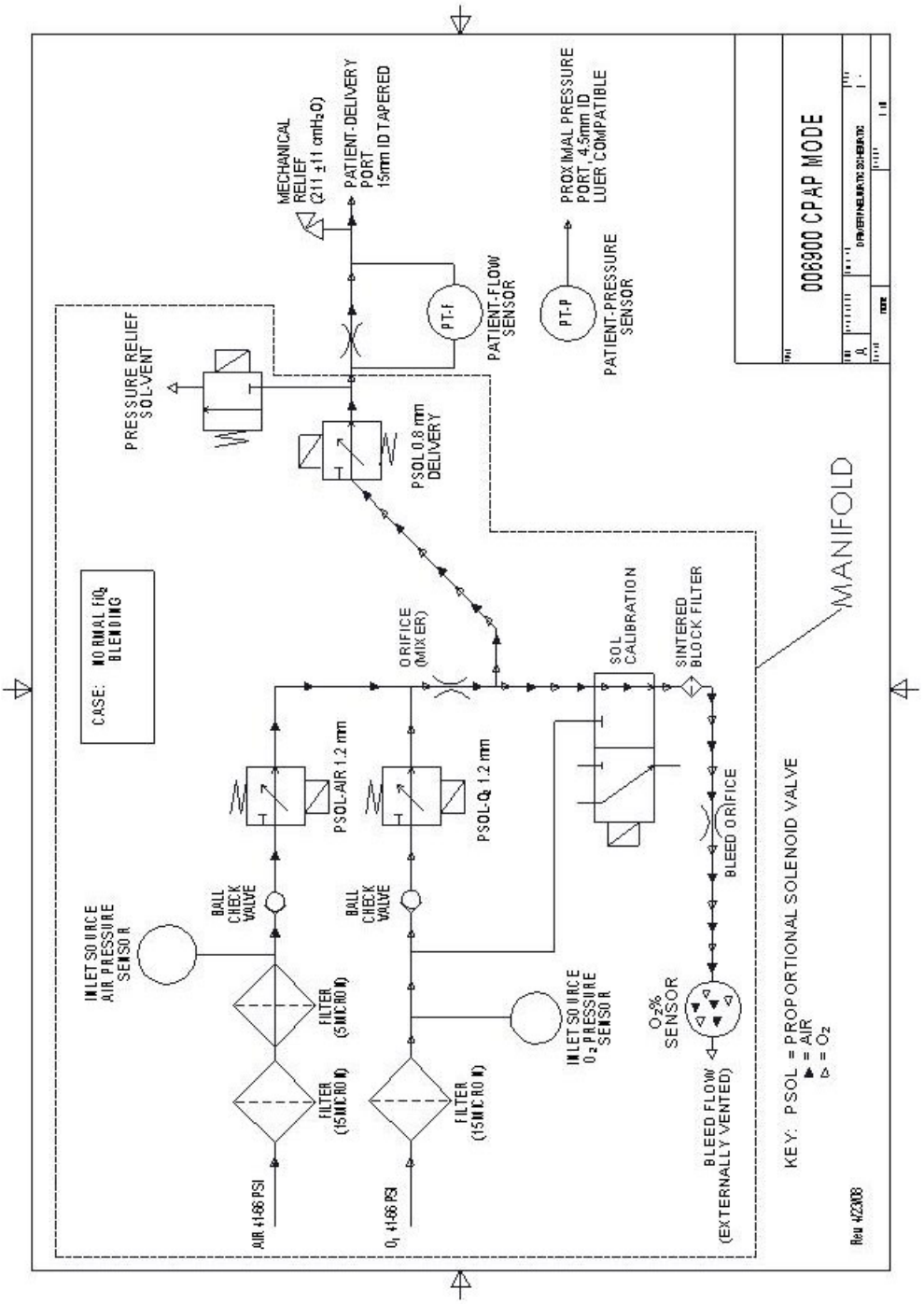
Warning Screen	Description	Possible Fault	Suggested Action
Power-On Self Test Warning Screens			
	Indicates that the inlet gas source (or sources, as indicated in the specific Warning Screen) is/are below the minimum specified operating range.	Air and/or Oxygen gas sources are not connected or below the minimum specified range	Connect and/or adjust the gas source inlet pressure(s) to within the specified tolerance of 41 – 66 psig
		Clogged inlet filter screens	Inspect and/or replace the inlet filter screens
		Faulty or defective inlet pressure sensor(s)	Service and/or replace the Manifold Assembly
	Indicates that the inlet gas source (or sources, as indicated in the specific Warning Screen) is/are above the maximum specified operating range.	Air and/or Oxygen gas sources are above the maximum specified range	Adjust/regulate the gas source inlet pressure(s) to within the specified tolerance of 41 – 66 psig
		Faulty or defective inlet pressure sensor(s)	Service and/or replace the Manifold Assembly

Warning Screen	Description	Possible Fault	Suggested Action
WARNING Pressure Calibration Failure Remove Device From Service	Indicates that the patient pressure sensor failed the zero point calibration during the Power-On Self Test.	Pressure is elevated in the patient circuit during start-up	Disconnect the proximal pressure line from the Device's receptacle to ensure pressure is not trapped and cycle power to the device.
		Faulty or defective patient pressure sensor	Service or replace the Outlet Fitting Assembly
WARNING Flow Calibration Failure Remove Device From Service	Indicates that the flow sensor failed the zero point calibration during the Power-On Self Test.	Source Valve and Delivery Valve failure.	Service and/or replace the Manifold Assembly.
		Faulty or defective flow sensor	Service or replace the Outlet Fitting Assembly.
WARNING Oxygen Calibration Error Remove Patient from Device and Cycle Power or Remove Device From Service	Indicates that the 2-point O_2 sensor calibration criteria are not met	Insufficient bleed flow (<0.9 lpm at 50 psig)	Perform PM service to inlet filter screens, air inlet filter bowl media, and O_2 sensor filters
			Service or replace the Manifold Assembly
			Check for occluded Oxygen Sensor Bleed Port
			Check for clogged inlet filter screens
		Faulty or defective O_2 sensor	Service or replace the Divider/Oxygen Sensor Assembly
Patient Treatment Mode Warning Screens			
WARNING Battery Drained Remove Device From Service	Indicates that the battery power level is below the minimum required to reliably operate the device	Running on DC power longer than the specified duration of 4 hours	Apply AC power to the device and allow the battery to charge for a minimum of 16 hours for a full charge
		Battery has exceeded its useful life	Replace the Battery Assembly
WARNING Software Failure Detected Please note the following code: M23L859 Remove Device From Service	Indicates that a fatal software fault has been detected by the device	Software fault or detection of a fault condition based on watchdog criteria that may adversely affect the operation of the device	Remove device from service. Note displayed code and re-install the latest revision of software

Warning Screen	Description	Possible Fault	Suggested Action
	Indicates that a non-fatal software fault has been detected by the device	Software fault or detection of a fault condition based on watchdog criteria that would not adversely affect the operation of the device	Note the displayed code and select the "accept" to return to the patient treatment screen. When able, remove device from the patient and cycle power to the device.
	Indicates that the O_2 sensor calibration criteria were not met during the routine/ automatic O_2 Sensor drift check/ calibration. The device will continue to deliver the CPAP therapy while this alarm is active using the previous calibration points	Insufficient bleed flow (<0.9 lpm at 50 psig)	Remove device from service and perform PM service to inlet filter screens, air inlet filter bowl media, and O_2 sensor filters
			Service or replace the Manifold Assembly
		Faulty O_2 sensor or excessive sensor drift	Service or replace the O_2 sensor assembly
	Indicates that the Oxygen source pressure has dropped below the specified minimum of 41 psig. User may opt to remove the device from service or select AIR ONLY mode (FiO_2 will go to 21%)	Oxygen source has become disconnected, tank has run out, or the hose/ fittings are leaking excessively	Follow on-screen commands and reconnect oxygen source, replace tank, or fix leak. The driver will automatically resume oxygen blending to the original FiO_2 setting when the O_2 source has been replenished or the leak is resolved.
		Clogged inlet filter screen	Remove from service and perform PM service to inlet filter screens
		Faulty inlet pressure sensor	Remove device from service and service/repair the Manifold Assembly
	Indicates that the Oxygen source pressure has exceeded the specified maximum of 66 psig. User may opt to remove the device from service or select AIR ONLY mode (FiO_2 will go to 21%)	Oxygen source pressure exceeds the maximum specified	Fix Oxygen source pressure and/or regulate the inlet pressure between 41 – 66 psig
		Faulty inlet pressure sensor	Remove device from service and service/repair the Manifold Assembly

Warning Screen	Description	Possible Fault	Suggested Action
	Indicates that the Air source pressure has dropped below the specified minimum of 41 psig. User may opt to remove the device from service or select OXYGEN ONLY mode (FiO_2 will go to 100%)	Air source has become disconnected, tank has run out, or the hose/ fittings are leaking excessively	Follow on-screen commands and reconnect air source, replace tank, or fix leak. The driver will automatically resume oxygen blending to the original FiO_2 setting when the Air source has been replenished or the leak is resolved.
		Clogged inlet filter screen	Remove from service and perform PM service to inlet filter screens
		Faulty inlet pressure sensor	Remove device from service and service/repair the Manifold Assembly
	Indicates that the Air source pressure has exceeded the specified maximum of 66 psig. User may opt to remove the device from service or select OXYGEN ONLY mode (FiO_2 will go to 100%)	Air source pressure exceeds the maximum specified	Fix Air source pressure and/or regulate the inlet pressure between 41 – 66 psig
		Faulty inlet pressure sensor	Remove device from service and service/repair the Manifold Assembly
	Indicates the warnings associated with delivering high FiO_2 for prolonged periods of time. This screen will appear and must be accepted in order to enter OXYGEN ONLY mode	Mandatory warning screen that appears if OXYGEN ONLY mode is imminent due to the loss of the Air source (air source outside of specification)	Follow on-screen commands and reconnect Air source, replace tank, or fix leak. The driver will automatically resume oxygen blending to the original FiO_2 setting when the Air source has been replenished or the leak is resolved.

16. PNEUMATIC DIAGRAM



17. ELECTROMAGNETIC COMPATIBILITY

The following information is directed by the Standard IEC 60601-1-2:2001 for Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

WARNING

The use of any power cords with the Air*Life*® nCPAP System Driver other than those supplied with the driver may result in increased emissions and/or decreased Immunity of the Air*Life*® nCPAP System Driver.

Table 2: Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The Air*Life*® nCPAP System Driver is intended for use in the electromagnetic environment specified below. The customer or user of the Air*Life*® nCPAP System Driver should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
CISPR 11 RF Emissions	Group 1	The Air*Life*® nCPAP System Driver uses RF energy only for its internal function. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
CISPR 11 RF Emissions	Class B	The Air*Life*® nCPAP System Driver is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic Emissions	Not Applicable	
IEC 61000-3-3 Voltage Fluctuations, Flicker Emissions	Not Applicable	

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The Air*Life*® nCPAP System Driver is intended for use in the electromagnetic environment specified below. The customer or user of the Air*Life*® nCPAP System Driver should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment—Guidance
IEC 61000-4-2 Electro-Static Discharge (ESD)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-4 Electrical Fast Transient, Burst (EFT) (Note 2)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5 Power Line Surge (Note 2)	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
IEC 61000-4-8 Power Frequency Magnetic Field (50/60 Hz)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations (Note 2)	<5 % *U*T (Note 1) (>95 % dip in UT) for 0.5 cycle	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Air*Life*® nCPAP System Driver requires continued operation during power mains interruptions, it is recommended that the Air*Life*® nCPAP System Driver be powered from a non-interruptible power supply or a battery.
	40 % *U*T (60 % dip in *U*T) for 5 cycles	40 % *U*T (60 % dip in *U*T) for 5 cycles	
	70 % *U*T (30 % dip in *U*T) for 25 cycles	70 % *U*T (30 % dip in *U*T) for 25 cycles	
	<5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 5 sec	

Note 1—*U*T is the AC mains voltage prior to application of the test level.
Note 2—Performed with an Input Voltage of 120 V AC only.

Table 4: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The Air*Life*® nCPAP System Driver is intended for use in the electromagnetic environment specified below. The customer or user of the Air*Life*® nCPAP System Driver should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Air*Life*® nCPAP System Driver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
IEC 61000-4-6 Conducted RF	3 V rms 150 kHz to 80 MHz	3 V rms	$d = 1.2\sqrt{P}$
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \frac{1.2\sqrt{P}}{E_1}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[a] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the Air*Life*® nCPAP System Driver is used exceeds the applicable RF compliance level above, the Air*Life*® nCPAP System Driver should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Air*Life*® nCPAP System Driver.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 5: Recommended separation distances between portable and mobile RF communications equipment and the Air*Life*® nCPAP System Driver

The Air*Life*® nCPAP System Driver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or user of the Air*Life*® nCPAP System Driver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Air*Life*® nCPAP System Driver, as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

18. MRI NOTICE

This equipment contains electromagnetic components whose operation can be affected by intense electromagnetic fields.

Do not operate this device in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or short-wave therapy equipment. Electromagnetic interference could disrupt the operation of the device.

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19. WARRANTY INFORMATION

This is the standard warranty for the Air*Life*® nCPAP System Driver and is extended only to the buyer purchasing the said product directly from Cardinal Health, Inc. (hereinafter referred to as Cardinal Health) or from an authorized dealer, distributor, or agent as new merchandise.

The Air*Life*® nCPAP System Driver is warranted for a period of two years (24 months) from the date of delivery to be free from manufacturing defects and to conform to the description thereof contained in the relevant Operation and Routine Maintenance Manual. This warranty does not cover normal maintenance such as cleaning, adjustment or updating of equipment parts. Internal batteries are warranted for one year from the date of receipt.

Cardinal Health's sole obligation under this warranty is limited to the replacement or repair of the product or parts thereof which upon examination are found to contain manufacturing defects or not to conform to the description thereof contained in the relevant manual. Cardinal Health will not be liable for consequential damages.

The foregoing warranty shall not apply if the product or any part thereof has (i) been repaired or altered by anyone other than an authorized representative of Cardinal Health without written consent (ii) subjected to abuse, misuse, negligence or accident (iii) operated under conditions other than normal use (iv) the prescribed periodic maintenance and/or services have not been performed as specified in the relevant manual.

There are no warranties that extend beyond this warranty and the description of the products contained in the relevant Operator's & Routine Maintenance Manual. Cardinal Health makes no warranty as to merchantability with respect to the products. This warranty is given in addition to statutory warranty and in no way affects the purchaser's statutory rights.

Disclaimer

The Cardinal Health guarantee will only be effective on condition that the product is used for the specific intention for which it was designed and operated as given in the Operator's & Routine Maintenance Manual. Any reuse of single use products, or use of the equipment in conjunction with, or while attached to non-approved equipment will automatically void any guarantee or warranty in force. Cardinal Health will not accept any liability for any injury or damage to persons or property resulting from a breach of these conditions. Cardinal Health will only guarantee product supplied if it has been serviced in accordance with procedures given in the Service Manual, by hospital service personnel or authorized representatives who have been trained by Cardinal Health and providing that the product has not been modified, altered or changed unless specifically authorized to do so in writing by Cardinal Health.

20. TECHNICAL SERVICE

Contact Technical Service for:

- Service
- Service Manual (copy)
- Parts List
- Technical Questions

Phone # 800-231-2466

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